APPENDIX A

United States Court of Appeals
for the Federal Circuit

02-1532, -1559

CARDIAC PACEMAKERS, INC.,
GUIDANT SALES CORPORATION, and
ELI LILLY AND COMPANY,

Plaintiffs-Appellants,

and

ANNA MIROWSKI,

Plaintiff-Appellant,

v.

ST. JUDE MEDICAL, INC.,
PACESETTER, INC., and
VENTRITEX, INC.,

Defendants-
Cross Appellants.

DECIDED: August 31, 2004

Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

NEWMAN, Circuit Judge.

This patent infringement action was brought by Cardiac Pacemakers, Inc., Guidant Sales Corp., Eli Lilly and Company, and Anna Mirowski (collectively "CPI") against St. Jude Medical, Inc., Pacesetter, Inc., and Ventritex, Inc. (col-

lectively "St. Jude"), in the United States District Court for the Southern District of Indiana.[1] The appeal relates to United States Patent No. 4,407,288, entitled "Implantable Heart Stimulator and Stimulation Method," inventors Alois A. Langer, Steve A. Kolenik, Marlin S. Heilman, Mieczyslaw Mirowski, and Morton M. Mower. We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial of infringement and reassessment of damages. We affirm the district court's decision upholding the patent term extension.

THE PATENTED INVENTION

The pumping action of the human heart occurs by electrical stimulation of various parts of the heart muscle, a complex process flowing from the nervous and other bodily systems. Heart arrhythmias result from disturbances in this process, whereby the heart may beat too slowly (bradycardia), too rapidly (tachycardia), or in an erratic, disorganized, or quivering fashion (fibrillation). Arrhythmias may occur in varying degrees. In treating such heart abnormalities it is important to determine the form and degree of arrhythmia present, as well as to identify the section or sections of the heart in which the arrhythmia originates, such as the ventricles or the atria. The treatment must be appropriate to the specific abnormality.

The inventions subject of this lawsuit are implantable cardiac defibrillators (ICDs) that are permanently installed under the skin, and that determine abnormal cardiac activity

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[1] *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, NO. IP 96-1718-C H/G, 2000 U.S. Dist. LEXIS 17352 (S.D. Ind. Nov. 29, 2000) (Claim Construction); *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, NO. IP 96-1718-C H/G, 2002 U.S. Dist. LEXIS 14767 (S.D. Ind. July 5, 2002) (Amended Final Judgment).

and treat that activity by delivering electrical shocks to the heart muscle in appropriate strengths. The first successful ICDs were developed in about 1980 by a team led by the late Dr. Mieczyslaw Mirowski, an inventor of the patents in suit. In the district court two patents were in suit, for improved ICDs whereby the ICD evaluates the abnormal heart activity, determines the pattern of electrical stimulation needed to treat the type of arrhythmia exhibited by the heart, delivers the appropriate electrical pulses or shocks, and changes the pulses as necessary for optimum treatment. United States Patent No. 4,316,472 (the '472 patent) is for an improved ICD whereby the implanted device analyzes the arrhythmia, and the requisite energy levels for electrical shocks to the heart are calculated and externally programmed. Patent No. 4,407,288 (the '288 patent) is for a further improvement that continuously determines the nature of an arrhythmia as it occurs, and selectively performs multi-mode therapy. Multi-mode therapy includes administering relatively mild pacing shocks to correct mild arrhythmias, intense shocks to correct fibrillation, and shocks appropriate to correct cardioversion, which the district court defined as "the application of non-pacing electrical pulses designed to stimulate sufficient heart tissue to correct an arrhythmia, with energy levels generally below those used for defibrillation." The cardioversion capability is basic to this appeal.

CPI charged St. Jude with infringement of claims 1 and 18 of the '472 patent and claims 4 and 13 of the '288 patent. The jury found St. Jude liable for infringement of the '472 patent, but not the '288 patent. The jury found both patents valid, and rejected St. Jude's charge that the '288 patent is unenforceable for inequitable conduct during patent prosecution. The jury awarded damages of $140 million for infringement of the '472 patent.

On post-trial motions the district court granted JMOL in favor of St. Jude on most of the issues on which CPI had

prevailed in the jury verdict. The court held that the claims of both the '472 patent and the '288 patent are invalid and not infringed, and granted a conditional new trial in the event of reversal on appeal. The court also granted St. Jude's motion for sanctions based on witness misconduct, and awarded partial attorney fees to St. Jude based on Cardiac Pacemakers' failure to comply with certain discovery obligations.

No appeal is taken as to the '472 patent. CPI appeals the judgment of invalidity and non-infringement of the '288 patent, and requests reinstatement of the jury verdict. St. Jude cross appeals the court's ruling, as a matter of law, that patent term extension was properly granted.

I

VALIDITY

At issue are claims 4 and 13 of the '288 patent. Claim 4, and claim 1 from which it depends, state:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:
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> (a) determining a condition of the heart from among a plurality of conditions of the heart;
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> (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
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> (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

4. The method of claim 1, wherein at least one mode of operation of said implantable heart stimulator includes cardioversion.

Claim 13, and claim 10 from which it depends, state:

10. An implantable heart stimulator capable of monitoring and detecting a plurality of arrhythmias, and capable of being programmed to undergo a single or multi-mode of operation corresponding to a respective arrhythmia to treat automatically the detected arrhythmia, said stimulator comprising:

determining means for determining the occurrence of one of a plurality of conditions of the heart;

selecting means responsive to said determining means for selecting at least one mode of operation of said implantable heart stimulator corresponding to a respective one of said plurality of conditions for automatically treating said determined conditions; and

executing means for executing a sequence of events defined by said at least one mode of operation, whereby to treat said determined condition.

13. The stimulator of claim 10, wherein said at least one mode of operation includes cardioversion.

Granting judgment of invalidity as a matter of law, the district court ruled that Claims 4 and 13 are invalid on the ground of obviousness and for failure to disclose the best mode of making and using the invention.

Obviousness

In review of a jury verdict on the ground of obviousness, the underlying findings of fact, whether explicit or presumed as necessary to support the verdict, are reviewed for substan-

tial evidentiary support; and the ultimate question of obviousness is reviewed for correctness in law, based on the factual premises. *See Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1319 (Fed. Cir. 2003); *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001). These standards are applied by the district court upon motion for judgment as a matter of law, and again by the appellate court upon grant or denial of that motion. *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.*, 248 F.3d 1303, 1309 (Fed. Cir. 2001) ("This court reviews a district court's grant of JMOL de novo and reapplies the JMOL standard.") (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)).

CPI argues that the jury verdict must be upheld because there was substantial evidence at trial whereby a reasonable jury could have sustained the validity of the patent on the ground of obviousness, pointing out that issued patents can only be proved invalid by clear and convincing evidence. *See, e.g., Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 988 (Fed. Cir. 1989) (reviewing the verdict in light of the burden of proof).

At the trial each side explained what the cited references taught, as well as the general knowledge in this field of technology at the time the invention was made. The jury was instructed that:

> The suggestion [to combine elements from separate references] can be expressly stated in a particular reference or it can be within the knowledge that was generally available to one of ordinary skill in the art.

Jury Instruction No. 46. Prior knowledge in the field of the invention must be supported by tangible teachings of reference materials, and the suggestion to combine references must not be derived by hindsight from knowledge of the in-

vention itself. *See Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1578-79 (Fed. Cir. 1997) ("However, the record must provide a teaching, suggestion, or reason to substitute computer-controlled valves for the system of hoses in the prior art. The absence of such a suggestion to combine is dispositive in an obviousness determination."); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.").

CPI's witnesses testified that the '288 invention was not a simple combination of known steps, but a complex solution to a difficult problem, achieved amid skepticism concerning the feasibility of producing a single implantable device that could detect and treat a wide range of heart abnormalities. St. Jude's witnesses disagreed with CPI as to the unobviousness of the combination. Evidence was presented to the jury of a long-felt but unmet need to achieve multi-mode detection and stimulus capability that included cardioversion. There was evidence that cardioversion was not treatable by existing multi-mode ICD's, and there was evidence of skepticism that such multi-mode treatment could be achieved. The jury found that invalidity of the '288 patent on the ground of obviousness had not been proved.

The district court, granting St. Jude's motion for judgment as a matter of law, found that each of the elements of claims 4 and 13 was previously known. The court cited references that described implanted cardiac devices that provided multimode therapy, although none included cardioversion therapy. The court found that cardioversion therapy was known, and found that "compelling motivation" to combine therapies in a single implanted device was provided by an article by Haft, wherein Haft explained that pacing therapy may trigger ventricular fibrillation. The district court found

that Haft identified the problem solved by the '288 patent, and concluded that it would have been obvious to design a pacing device that could defibrillate if necessary. That is, the court found that there was a known need to treat mixtures of arrhythmias, and that it would have been obvious to combine known methods of separate treatment.

Among the cited references, the district court placed weight on a British patent 2,026,870 to Duggan, as providing the motivation to combine treatments of different arrhythmias. Duggan discusses cardioversion achieved by application not of a single large shock, as in the '288 patent, but by a combination of small pacing shocks delivered simultaneously to multiple sites on the heart. CPI's expert explained that what Duggan taught was a form of pacing and not true cardioversion, and concluded that Duggan does not propose the combination of therapies provided by the '288 patent, or teach how to achieve a device that produces this combination.

We think that the district court, in granting JMOL, applied an incorrect standard to the ultimate question. Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure.

There can of course arise situations wherein identification of the problem is itself the invention. But in the case at bar the problem was well-recognized: the problem of treating complex cardiac arrhythmias. The solution of this problem, according to the trial proceedings, had not previously been achieved. It was undisputed that before the work of Dr. Mirowski and his team there was no implantable device that was capable of treating the combination of abnormal ar-

rhythmias including cardioversion. Recognition of an unsolved problem does not render the solution obvious.

Expert witnesses for each side presented opposing opinions as to the unobviousness of the Mirowski invention. St. Jude's expert testified that in his opinion persons of ordinary skill in the relevant field would have been motivated to modify Duggan "if one felt it [cardioversion] would be better accomplished with a single high energy shock." CPI's expert testified that the Duggan reference teaches away from use of high-energy shock because Duggan is concerned only with power consumption in ICDs. St. Jude stressed the obviousness of high energy cardioversion or defibrillation shocks due to the statement in the Haft article that "antitachycardia pacing could induce fibrillation." CPI presented contrary expert opinion, stressing that no reference teaches combining cardioversion with other cardiac therapies in a single device, or states that it is feasible to do so.

It was not disputed that before the '288 invention this combination of modes of treatment had not been achieved. CPI pointed out that claim 4 requires cardioversion, not defibrillation, and that the Haft article is concerned with fibrillation. The jury heard testimony that defibrillation shocks, not cardioversion shocks, revert fibrillation. The jury also heard testimony that defibrillation energy levels are different from cardioversion energy levels. While the jury also heard testimony that "cardioversion and defibrillation are so similar to practically be the same therapy," other witnesses disputed this position.

Whether the prior art provides the suggestion or motivation or teaching to select from prior knowledge and combine it in a way that would produce the invention at issue is a question of fact. *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 (Fed. Cir. 2000). These issues were extensively explored at the trial, including evidence of the commercial success and the interest of others in licensing the Mi-

rowski inventions. The record contains substantial evidence whereby a reasonable jury could have reached the verdict that it would not have been obvious in March 1981 to provide an ICD that includes cardioversion. In view of this evidentiary support, the district court's grant of JMOL cannot stand. *See Continental Air Lines, Inc. v. Wagner-Morehouse, Inc.*, 401 F.2d 23, 30 (7th Cir. 1968)[2] (the jury verdict must be sustained, even if the judge would have reached a different conclusion, if the verdict is supported by substantial evidence). The grant of JMOL is reversed, and the jury verdict is reinstated that the '288 patent is not invalid for obviousness.

Best Mode

St. Jude also presented the defense that the '288 patent is invalid for failure to set forth the best mode of practicing the invention. The jury found that the patents were not invalid on this ground. On St. Jude's post-trial motion the district court ruled that the best mode requirement was violated, and granted judgment of invalidity as a matter of law. On this question of fact, we review the evidentiary record for substantial evidence supporting the jury verdict.

A best mode violation requires that the inventor knew of and concealed a better mode than was disclosed for making and using the claimed invention. *Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 588 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the claimed invention that sec-

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[2] We apply the procedural law of the regional circuit in reviewing the procedure underlying the district court's post-trial determinations. *See National Presto Indus. v. West Bend Co.*, 76 F.3d 1185, 1188 n.2 (Fed. Cir. 1996) ("On procedural matters not unique to the areas that are exclusively assigned to the Federal Circuit, the law of the regional circuit shall be applied.")

tion 112 para. 1 is designed to prohibit.") (emphasis in original); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) ("in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed").

The best mode requirement differs from the enablement requirement, for failure to enable an invention will produce invalidity whether or not the omission was deliberate, whereas invalidity for omission of a better mode than was revealed requires knowledge of and concealment of that better mode. *See In re Gay*, 309 F.2d 769, 772 (CCPA 1962) (best mode requirement precludes inventors "from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived"). Thus the inventor must disclose the best mode of what he claims as his invention. *See also, e.g., Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1575 (Fed. Cir. 1992) ("Invalidity for violation of the best mode requires intentional concealment of a better mode than was disclosed . . . .") The question here raised relates to the best mode obligation with respect to subject matter that is not part of the invention, but that is used in conjunction therewith—here the battery for use with these battery-powered ICDs.

St. Jude argued at trial that the inventors were required to include in the patent specification the best battery known to them at the time the patent application was filed. The inventors had asked Honeywell to develop an improved battery for use in these cardiac devices; Honeywell did so, and about four months before the '288 application was filed Honeywell published an article at the Power Sources Conference, describing the battery that it developed. The inventors testified that a battery was not part of their invention, that the Honeywell and other batteries for ICDs were known when the '288

application was filed, that various known batteries were usable in their device, that in the evolving battery art other batteries were being developed, and that they actually chose a different battery for their commercial device. The inventors stressed that their invention was not about batteries, that there was no intent to conceal the Honeywell or any battery, and that it was not concealed. St. Jude argued that a battery was necessary to operate the device, that the Honeywell battery should have been mentioned, and that not mentioning it amounted to culpable concealment. The jury found in favor of CPI on this question.

The district court, reversing the jury verdict, held that the inventors were required to include the Honeywell battery in the patent specification, since it was the best battery then known to them. The court deemed it insufficient that Honeywell had publicly described and published the battery, and found that Honeywell's publication was in "a forum for battery specialists, not for cardiologists and inventors of ICDs." The court held that failure to include the Honeywell battery in the specification invalidated the patent on best mode grounds.

CPI states that the district court erred in law, pointing out that the invention is not about batteries, that the Honeywell battery was known, and that there was no evidence or basis for inference of intent to conceal the battery. The obligation to disclose the best mode relates to the invention that is described and claimed. *See Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 1532 (Fed. Cir. 1991) ("The best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims.") Subject matter that is not part of the invention that is claimed need not be included in the specification, and thus is not subject to the best mode requirement. As explained in *Engel*, 946 F.2d at 1532-33, "the reasons are pragmatic: the disclosure would be boundless, and the pitfalls endless."

There was evidence before the jury that persons knowledgeable in the field of the invention would know the sources of batteries for pacemakers and related devices. There was no evidence of concealment, and the jury had evidence that the Honeywell battery was published in a publication for battery specialists. There was substantial evidence whereby a reasonable jury could have found that the best mode requirement had not been violated. The grant of JMOL on this issue is reversed, and the jury verdict is reinstated.

The Conditional New Trial

On the validity issues, the district court granted a new trial in the event of our reversal of the grant of judgment as a matter of law. We review the grant of a new trial in accordance with Seventh Circuit standards, *see* n.2 *supra*, as stated in, *e.g.*, *Billy-Bob Teeth, Inc. v. Novelty, Inc.*, 329 F.3d 586, 590-91 (7th Cir. 2003) ("We review a grant of a new trial for abuse of discretion. A new trial may be granted only when the verdict is against the manifest weight of the evidence.")

The jury verdicts on the issues of obviousness and best mode were not against the manifest weight of the evidence. *See Continental Air Lines*, 401 F.2d at 30 ("If the evidence in the record, viewed from the standpoint of the successful party, is sufficient to support the jury verdict, a new trial is not warranted merely because the jury could have reached a different result. Neither the trial court nor this Court may substitute its judgment for that of the jury on disputed issues of fact.") (quoting *Gebhardt v. Wilson Freight Forwarding Co.*, 348 F.2d 129, 133 (3d Cir. 1965)). Further, there was no issue of prejudicial procedural error or incorrect instruction of law. In these circumstances the conditional grant of a new trial exceeded the court's discretionary authority, and is vacated.

INFRINGEMENT

The jury found that claims 4 and 13 of the '288 patent are not infringed. Only the judgment as to claim 4, the method claim, is appealed.

CPI argues that the district court incorrectly construed claim 4 as being in the form of 35 U.S.C. § 112 ¶ 6, and thereby incorrectly instructed the jury with respect to infringement. CPI argues that on the correct claim construction, the undisputed facts establish that the accused devices infringe claim 4. St. Jude disagrees, and also states that the misconduct of one of CPI's expert witnesses so tainted the issue of infringement that in all events a new trial of infringement is required if this court modifies the claim construction. The district court sustained the verdict of non-infringement, and granted a conditional new trial on the ground of witness misconduct.

Procedural Matters

St. Jude states that CPI failed to preserve a right to appeal the claim construction, because CPI did not make formal objection when the jury was instructed on the claim construction. CPI responds that the claim construction was decided at the *Markman* hearing, and was not a proper subject of trial objection under Rule 51. St. Jude counters that all objections must be raised at the specified times during a jury trial, or they are waived. Thus St. Jude states that CPI has no right to appellate review of the claim construction that was decided at the *Markman* hearing and on which the jury was instructed and the trial conducted.

Rule 51 prevents a party from assigning error to an incorrect jury instruction that could have been corrected if the error had been timely raised. A party must warn the court and the opposing party that there has been an error of law. Here, the asserted error was the decision of the *Markman* hearing, held well before trial. The district court's construc-

tion of the claims was resolved in that decision, and was the subject of a written decision issued some six months before trial. The jury was instructed in accordance with that decision.

CPI points out that the issues of claim construction had been fully argued and briefed at the *Markman* hearing, and that its disagreement concerning § 112 ¶ 6 was well known to the district court during that hearing. CPI refers to the "futility" exception, recognized by the Seventh Circuit in *Chestnut v. Hall*, 284 F.3d 816, 820 (7th Cir. 2002) ("A party may be excused from complying with the formalities of Rule 51 where: (1) the party's position has been previously made clear to the court; and (2) further objection would be unavailing and futile.") (citing *Carter v. Chicago Police Officers M.L.*, 165 F.3d 1071, 1078 (7th Cir. 1998)). *Cf. Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1369-70 (Fed. Cir. 2002) (applying regional circuit law to rule 51 and the futility exception).

When the claim construction is resolved pre-trial, and the patentee presented the same position in the *Markman* proceeding as is now pressed, a further objection to the district court's pre-trial ruling may indeed have been not only futile but unnecessary. In this case the court's claim construction resulted from a hearing at which all parties' positions were presented, and the applicability of § 112 ¶ 6 to the claims was extensively argued. The issue was complex, and it was fully litigated to the court, who announced its decision before the jury was instructed. Objection under Rule 51 was not required to preserve the right to appeal the *Markman* ruling.

Claim Construction

CPI argues that the district court incorrectly construed clause (a) of claims 1 and 4:

> (a) determining a condition of the heart from among a plurality of conditions of the heart.

The court held that clause (a) is in the step-plus-function form of § 112 ¶ 6.[3] Implementing that holding, the court ruled that clause (a) "is limited to detecting and distinguishing among arrhythmia by analyzing the outputs of rate circuitry and PDF [probability density function] circuitry," the process in the '288 specification. The jury was instructed that unless a combination of rate output and PDF circuitry or the equivalent thereof was used in the St. Jude device, the claim was not infringed.

CPI states that this claim construction is incorrect, that clause (a) is not in § 112 ¶ 6 form and is not converted to that form simply because the preamble of the claim states that the invention is "the method comprising the steps of:". *See* claim 1, *ante*. CPI states that clause (a) simply recites a step that is part of the claimed method, and that absent the signal "step for" there is a presumption that a step does not invoke § 112 ¶ 6. The district court disagreed, stating that if clause (a) were construed as CPI proposes, it would "allow[] CPI to claim all possible methods of detecting heart arrhythmia." Concluding that the patent would thus "sweep[] too broadly," the court ruled that clause (a) covers only the specific procedures in the specification for determining the condition of the heart, and technologic equivalents of those procedures.

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[3] 35 U.S.C. § 112 ¶ 6. An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

CPI is correct that "claiming a step by itself, or even a series of steps, does not implicate § 112 ¶ 6," as explained in *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997). Thus clause (a) was inappropriately assigned to § 112 ¶ 6. However, removal of clause (a) from § 112 ¶ 6 does not automatically convert it into an open-ended step without limits. A claim limitation is always construed in light of the specification, whatever the form of the claim. *See, e.g., Kinik Co. v. International Trade Comm'n*, 362 F.3d 1359, 1365 (Fed. Cir. 2004) ("The words of patent claims have the meaning and scope with which they are used in the specification and the prosecution history."); *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998) ("The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history."); *Grain Processing Corp. v. American Maize Products Co.*, 840 F.2d 902, 908 (Fed. Cir. 1988) ("All claims must be construed in light of the specification and the prosecution history.").

CPI argues that upon the correct claim construction the "determining" step is not limited to any particular procedure, because the specification makes clear that various methods may be used to determine the condition of the heart. The specification, after describing the PDF circuitry, states that "conventional logic circuitry" can be used:

> It is also to be noted that *conventional logic circuitry can be provided for determining*, based on the previously discussed inputs, the existence of various medical conditions, for example, ventricular tachycardia, ventricular fibrillation and super-ventricular tachycardia. Such conventional logic circuitry can be provided either in the dedicated cardiac state evaluation circuit 34, or in one of the processors/controllers to be discussed below.

'288 patent, col. 10, lines 19-28 (emphasis added). CPI argues that the invention is not based on how the cardiac condi-

tion is determined, but on the treatment that is applied to that condition. CPI states that the rate plus PDF method is simply a preferred embodiment, and that this limitation should not be imported into the claim.

We conclude that the district court erred in applying § 112 ¶ 6. Method claims necessarily recite the steps of the method, and the preamble words that "the method comprises the steps of" do not automatically convert each ensuing step into the form of § 112 ¶ 6. Nor does the preamble usage "steps of" create a presumption that each ensuing step is in step-plus-function form; to the contrary, the absence of the signal "step for" creates the contrary presumption. The district court's claim construction is modified accordingly; the "determining" step must be construed, as for all claim steps, in light of the specification and the prosecution history. We remand to the district court for that purpose.

Infringement

CPI states that if § 112 ¶ 6 is eliminated from the claim construction, judgment in favor of CPI is required. St. Jude states that if the claim construction is changed, at a minimum there should be a new trial of infringement.

CPI states that the jury reached the incorrect verdict of non-infringement of the '288 patent because of the incorrect claim construction. At the trial, on the instruction that only rate-plus-PDF detection circuitry or its technologic equivalent was covered by the claim, the jury found no infringement of the '288 patent. There was extensive evidence that St. Jude did not use a rate-plus-PDF procedure. CPI did present evidence to try to prove that the St. Jude circuitry is equivalent to PDF circuitry, and St. Jude presented contrary evidence. CPI argues that on the correct claim construction, any method of determining the condition of the heart would literally satisfy clause (a), and that the question of § 112 ¶ 6 equivalency should not have arisen. CPI argues that we can,

and should, find infringement as a matter of law once we correct the district court's claim construction.

St. Jude responds that if we modify the district court's claim construction, as we have, a new trial is required so it can present evidence and argument that were not needed under the district court's original claim construction, such as whether the now-asserted scope of the claims is supported by the specification. St. Jude points out that it is entitled to jury determination of the question of infringement. We agree. It is well established that when an incorrect jury instruction—such as an incorrect claim construction—removes from the jury a basis on which the jury could reasonably have reached a different verdict, the verdict should not stand. *See Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1201 (Fed. Cir. 2002) (an erroneous instruction on claim interpretation that affects the jury's verdict on infringement is grounds for a new trial); *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1373 (Fed. Cir. 2002) (same).

CPI is correct that a claim construction limited to § 112 ¶ 6 equivalency would remove the possibility of finding infringement if the CPI and St. Jude circuitries were not technologically equivalents but nonetheless determined the condition of the heart. We conclude that a new trial of infringement is required, for the question of infringement was not explored on the purportedly less restrictive claim construction that avoids § 112 ¶ 6. That question requires findings and conclusion by the trier of fact.

The Sanctions for False Testimony

The district court held that if a new trial of infringement is required, CPI should pay St. Jude's attorney fees for the new trial because of the misconduct of a CPI infringement

expert.[4] CPI argues that if the new trial of infringement is based solely on the district court's erroneous claim construction and is unrelated to the false testimony of the witness, the contingent sanction of attorney fees should be vacated.

The new trial here ordered is unrelated to the witness' deception; indeed, the jury rendered a verdict of noninfringement of the '288 patent despite his contrary testimony. Therefore the conditional sanction is vacated.

DAMAGES

The jury awarded damages of $140 million for infringement of the '472 patent. The district court granted JMOL of non-infringement of the '472 patent; that judgment is not appealed. CPI asks that the damages award be applied to the '288 patent, arguing that the same evidence was presented for both patents without distinction. St. Jude responds that the damages award cannot be shifted to a patent that the jury found not to be infringed, and argues that it is excessive in any event.

We conclude that it is inappropriate to shift the jury's damages award. The damages for infringement of the '288 patent, should infringement be found on remand, requires determination on remand.

PATENT TERM EXTENSION

St. Jude by cross appeal challenges the district court's ruling that the term of the '288 patent was properly extended under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act). The Act permits a pat-

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[4] The witness had concealed contradictory testimony that he had given in a related case. CPI has paid and is not appealing the sanctions already imposed, for St. Jude's attorney fees and expenses associated with the false testimony.

entee to obtain an extension of the patent term if marketing of the patented product was delayed due to federal regulatory review:

> 35 U.S.C. § 156(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—
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> . . . .
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> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
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> (5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is *the first permitted commercial marketing or use of the product* under the provision of law under which such regulatory review period occurred;
>
> (B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent;

(Emphasis added.)

Questions of statutory interpretation receive plenary review on appeal. *Warner-Lambert Co. v. Apotex Corp.*, 316

F.3d 1348 (Fed. Cir. 2003); *Hosiden Corp. v. Advanced Display Manufacturers*, 85 F.3d 1561, 1567 (Fed. Cir. 1996). The question here arises because the CPI device is not the first device covered by the '288 patent to receive FDA approval. CPI had granted licenses to two other companies for defibrillators, however, term extension was not requested based on the licensees' devices. In CPI's application for extension based on its PRx defibrillator, CPI stated that licenses had been granted for two other defibrillators covered by the '288 patent, the Ventritex V-100 and the Medtronic PCD, for each of which the licensee had obtained FDA approval. The Patent and Trademark Office and the FDA granted the extension based on the PRx approval period.

The district court held that extensions under subsection (5)(A) need not be based on the first FDA-approved medical device covered by the patent, but must be based on "the first permitted commercial marketing or use of the product" that is the basis of the application. The district court stated that the statute gives patentees a choice "in matching up products and the patents for which they seek extensions."

St. Jude argues that the district court erred, and that CPI's PRx defibrillator cannot be a basis for extension of the term of the '288 patent, no matter how independent its FDA approval procedure, because the Ventritex and Medtronic ICDs were previously approved and commercialized. CPI responds that when various devices, all requiring separate regulatory approval, are covered by the same patent, it suffices that the particular device on which the application for extension is based is covered by the patent and is subject to regulatory review, and that only one extension per patent is available.

The district court agreed with CPI, and held that § 156(a)(5)(A) does not require that the device on which the extension is based is the first approved product within the claims of the patent. The court stated: "The court should not

read into subparagraph (a)(5)(A) the limiting requirement that Congress imposed so clearly in writing subparagraph (a)(5)(B), but only for method patents primarily using recombinant DNA technology." The district court relied on the fact that § 156(a)(5)(A) refers to "marketing or use of *the* product" that the patentee has selected, whereas subparagraph (a)(5)(B), for DNA technology, refers to "the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent." In *Brown v. Gardner* the Court cautioned that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." 513 U.S. 115, 120, (1994) (quoting *Russello v. United States*, 464 U.S. 16, 23, (1983)).

St. Jude argues that the comparison between subparagraphs (a)(5)(B) and (a)(5)(A) is strained, and does not support the distinction drawn by the district court. St. Jude criticizes the weight the court gave to the change in text from "the" to "a," and directs attention to *Fisons, PLC v. Quigg*, 876 F.2d 99, 100-01 (Fed. Cir. 1989), wherein this court held that a drug-patent extension must be based on the first FDA approval of the active ingredient of the patented product because, under the definition in § 156(f)(2), the active ingredient is the approved "product." Thus in *Fisons* the court held that subsequent extensions were not available for subsequent products using the same active ingredient that was the basis of the first extension, implementing the principle that only one extension is available per approved product. *See Fisons*, 876 F.2d at 100 ("[I]t follows that because Fisons' patented new products containing cromolyn sodium did not qualify as the first permitted commercial marketing or use of the active ingredient cromolyn sodium, extensions of the patent term for the subject patents were not permissible.")

The district court agreed that only one extension was available, but held that the patentee was not required to rely on a licensee's version of the device as the basis for the extension. The legislative history supports this interpretation, for as originally proposed § 156(a) required that extensions "be granted only for the first approved product," H.R. Rep. No. 98-857, pt. 1, at 38 (1984), but that provision was removed from the legislation before enactment. *See Gulf Oil Corp. v. Copp Paving Co.*, 419 U.S. 186, 200 (1974) (Congress's failure to enact a proposed version of a statute "strongly militates against a judgment that Congress intended a result that it expressly declined to enact.")

The decision that extension was available based on CPI's PRx defibrillator is affirmed.

Lapse Due to Incorrect Payment of Maintenance Fees

St. Jude also argues that the '288 patent expired when CPI did not pay the correct maintenance fee, and that although the payment was later corrected and accepted by the Patent and Trademark Office, the patent must be deemed to have expired with the error, at least for purposes of term extension:

> 35 U.S.C. § 156(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section . . . if—
>
> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension.

The district court held that, in accordance with statute and regulation, the error had been corrected and the patent had not expired.

CPI points out that the statute provides for late payment and for correction of error without loss of rights, and that this was achieved. 35 U.S.C. § 41(c)(1) states:

> § 41(c)(1) If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.

St. Jude argues that this beneficence does not affect the requirement of § 156(a)(1) that the application for extension must be submitted before patent "expiration," and that the later revival of an expired patent does not overcome this stricture.

When the '288 patent was issued in 1983, the patentee was a "small entity" and qualified for reduced fees under 35 U.S.C. § 41(h)(1). From 1987 to 1998 the patentee paid the maintenance fees at the reduced rate applicable to small entities. However, in 1985 the '288 patent was non-exclusively licensed to a large entity, triggering the regulatory provision whereby the small entity status is lost to the patentee. *See* 37 C.F.R. § 1.9(d) (1985) (providing that small entity status is lost when any rights are licensed to any concern that does not qualify as a small entity). Meanwhile the patent was licensed to Eli Lilly & Company, which does not qualify as a small entity. In 1998 CPI advised the PTO of the error, stated that the erroneous payments as a small entity were made in good faith, and tendered the additional sums due and statutory penalties. The PTO accepted the late payments on October 16, 1998.

St. Jude argues that the patent expired in 1987 when the first incorrect maintenance fee was paid. However, the statute is explicitly contrary. *See* 35 U.S.C. § 41(c)(1) ("If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.") A similar issue was considered in *Ulead Systems, Inc. v. Lex Computer*

& Mgmt. Corp., 351 F.3d 1139 (Fed. Cir. 2003), wherein this court confirmed that the patent did not expire.

The district court correctly held that the '288 patent did not expire, and that the application for term extension was validly submitted. The decision on this issue is affirmed.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

APPENDIX B

United States District Court,

S.D. Indiana,
Indianapolis Division.

CARDIAC PACEMAKERS, INC.,
Guidant Sales Corporation, Eli Lilly and Company, and
Anna Mirowski, Plaintiffs,

v.

ST. JUDE MEDICAL, INC., Pacesetter, Inc., and
Ventritex, Inc., Defendants.

Cause No. IP 96-1718-CH/K.

July 5, 2002.

I. Introduction and Applicable Legal Standards

This action for patent infringement was tried to a jury from June 11 to June 29, 2001. On July 3, 2001, the jury rendered a mixed but complete verdict awarding plaintiffs $140 million in royalties for infringement of one patent applicable to implantable cardiac defibrillators. Numerous post-verdict motions from both sides challenge the verdict on every question the jury decided.

A. Parties, Products, and Verdict

Plaintiffs are Cardiac Pacemakers, Inc., Guidant Sales Corporation, Eli Lilly and Company, and Anna Mirowski. They are referred to collectively as "CPI" in this entry. Defendants are St. Jude Medical, Inc., Pacesetter, Inc., and Ventritex, Inc., and they are referred to collectively as "St. Jude."

The case was submitted to the jury on CPI's claims that St. Jude, beginning in 1997, infringed two claims each in U.S. Patent No. 4,316,472 (the '472 patent) and U.S. Patent No. 4,407,288 (the '288 patent), which claim inventions relating to implantable cardiac defibrillators (ICDs).[1]

ICDs are powerful and sophisticated life-saving electronic devices. An ICD is smaller than a deck of cards and is implanted in a patient's chest or abdomen with electrical leads that run to the patient's heart. An ICD can sense dangerous cardiac arrhythmias and can administer electrical therapy immediately, first with mild "pacing" shocks and, if necessary, with powerful defibrillating shocks that can save the life of a patient experiencing ventricular fibrillation.

The first successful ICDs were developed by a team led by Dr. Mieczyslaw Mirowski, the late husband of plaintiff Anna Mirowski. Dr. Mirowski and his team did pioneering work. Their inventions astonished many in the medical community who believed that such devices were impractical. The fundamental patent was issued to Dr. Mirowski and his team in 1976 for a "Cardioverting Device Having Single Intravascular Catheter Electrode System and Method for Its Use." *See* U.S. Patent No. 3,942,536 (Ex. 64). Dr. Mirowski and his team obtained a number of additional patents for improvements on the basic device. ICDs have been commer-

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[1] CPI originally alleged infringement of four patents. U.S. Patent No. 4,223,678 expired before trial during the arbitration of whether a license granted to Telectronics had transferred to St. Jude as part of an asset purchase. After the arbitration, CPI chose to drop its claims based on the '678 patent. The fourth patent was U.S. Patent No. 4,572,191, which this court held invalid before trial as a result of the claims construction process. *See* Docket No. 399.

cially and medically successful. They have saved thousands of lives.

Before this lawsuit arose, however, the fundamental '536 Mirowski patent had expired. The patents at issue in this trial deal with two significant features improving on the original invention. The '472 patent claims a device and accompanying method for which the energy levels for electrical shocks can be programmed externally, after the device has been implanted in a patient. The '288 patent claims a device and accompanying method that can be programmed for what is called "multimode" operation, meaning that the device can respond to an arrhythmia with one type of electrical therapy and then, if the first therapy is not successful, can proceed automatically to administer other types or modes of electrical therapy.

The jury's verdict produced a mixed result. The jury found that St. Jude had infringed the '472 patent for external programmability of energy levels. The jury also rejected St. Jude's defenses that the '472 patent is invalid for failure to comply with the written description requirement of 35 U.S.C. § 112 ¶ 1, for obviousness, and for obviousness-type double patenting. The jury also found that St. Jude's infringement was not willful.

The jury found that St. Jude had not infringed the '288 patent for multimode programming for ICDs. The jury also rejected St. Jude's defenses that the '288 patent is invalid for failure to comply with the best mode requirement of 35 U.S.C. § 112 ¶ 1 and for obviousness, and that the '288 patent should be unenforceable for inequitable conduct.

Turning to damages for infringement of the '472 patent, the jury found that CPI had not proven any lost profits. Instead, the jury awarded royalties, which it divided into a lump-sum initial payment of $110 million and a running royalty of $30 million through the expiration of the '472 patent on March 4, 2001, for a total damage award of $140 million.

B. Summary of Post Verdict Motions and Rulings

Over the years, Dr. Mirowski and his team have received praise and substantial royalties for their successful and pioneering work on lifesaving ICDs. *See* Tr. 1392 (CPI alone has paid royalties of more than $120 million for the Mirowski ICD patents). As shown in detail below, however, this is a case in which those interested in the patents have attempted to stretch too far the rewards of the patent system. This attempt was made by expanding patent claims beyond the written description, by double patenting, by violating the statutory best mode requirement, by procuring patents to obvious improvements on the basic invention, and by offering flimsy theories of infringement and even false testimony from the key expert witness.

The net result of the rulings in this entry is that the court is entering judgment for St. Jude on both patents and is conditionally granting a new trial for St. Jude as to most issues on which it did not prevail at trial. Rulings on several of St. Jude's requests for relief would be sufficient independently to support the court's final judgment with respect to both the '472 patent and the '288 patent. Nevertheless, the Federal Circuit has directed district courts to address all issues so that, in the event that a ruling on one issue is later reversed, another trial or other proceedings in the district court might not be necessary. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540-41 (Fed. Cir. 1983). Accordingly, the court rules as follows on these requests:

In Part II of this entry, the court grants St. Jude's motion for judgment as a matter of law finding Claims 1 and 18 of the '472 patent invalid for failure to comply with the written description requirement of 35 U.S.C. § 112 ¶ 1. The patent's written description covers devices and methods for treating arrhythmias only in the atria of the heart. The patent claims reach devices and methods for treating the entire heart, in-

cluding ventricular arrhythmias, which present very different problems. The limited written description did not convey to one of ordinary skill in the art that the inventors were in possession of a device and method for ventricular treatment. In the alternative, the court grants a conditional new trial on the written description defense. The evidence on the issue was overwhelming in favor of St. Jude.

In Part III, the court grants St. Jude's motion for judgment as a matter of law finding Claims 1 and 18 of the '472 patent invalid for obviousness-type double patenting. The court denies St. Jude's alternative request for a new trial on the issue, which can and should be decided as a matter of law in this case.

In Part IV, the court denies St. Jude's motion for judgment as a matter of law on its obviousness defense to Claims 1 and 18 of the '472 patent, as well as St. Jude's alternative motion for a new trial on the issue based on the weight of the evidence.

In Part V, the court grants St. Jude's motion for judgment as a matter of law finding that Claim 18 of the '472 patent has not been infringed, and in the alternative the court grants a conditional new trial on that issue based on the overwhelming weight of evidence. The court also grants St. Jude's motion for judgment as a matter of law finding that Claim 1 of the '472 patent was not infringed, but denies a conditional new trial on the issue.

With Part VI, the court turns to the '288 patent, which the jury found was valid but not infringed. In Part VI, the court grants St. Jude's motion for judgment as a matter of law finding Claims 4 and 13 of the '288 patent invalid because the inventors violated the "best mode" requirement of 35 U.S.C. § 112 ¶ 1 by failing to disclose the battery custom-designed for them at great expense. The court also grants St. Jude's alternative request for a conditional new trial based on the overwhelming weight of evidence on the issue.

In Part VII, the court grants St. Jude's motion for judgment as a matter of law finding Claims 4 and 13 of the '288 patent invalid as obvious from the prior art. The concept of "multimode" treatment in ICDs, including cardioversion as one of the modes, was obvious at the relevant time from extensive prior art. The court also grants a conditional new trial on the issue based on the manifest weight of the evidence.

In Part VIII, the court denies St. Jude's motion for judgment as a matter of law and its alternative motion for a new trial on its defense that the '288 patent should be unenforceable as a result of inequitable conduct by the patentee. Whether the patentee acted with deceptive intent was a question upon which reasonable people could differ. The jury could properly reject the defense.

In Part IX, the court grants St. Jude's motion for sanctions and for a conditional new trial as a result of the deception of CPI's chief expert witness, Dr. Joe D. Bourland. After the trial, Dr. Bourland admitted deliberately lying at trial and during his deposition so as to conceal matters that go to the heart of both his credibility and the merits of the case. Dr. Bourland's deception tainted the trial and rendered the partial but large verdict in favor of plaintiffs the product of an unfair proceeding. The court also imposes monetary sanctions on plaintiff Cardiac Pacemakers, Inc. for its failure to comply with its discovery obligations regarding Dr. Bourland and his deception.

In Part X, the court denies CPI's motion for a new trial on whether the '288 patent was infringed. Comments in St. Jude's opening statement, to which no timely objection was made, did not deny CPI a fair trial on the issue. The court's limited remedial actions taken during trial regarding what was then known about problems with Dr. Bourland's testimony also did not deny CPI a fair trial.

Finally, in Part XI, the court grants St. Jude's motion for a conditional new trial on the issue of royalties, though the

court denies St. Jude's motion for judgment as a matter of law on whether any lump sum initial royalty payment could be proper in the case. The court also denies CPI's conditional motion for a new trial on the issue of lost profits. The court does not reach CPI's motion for an award of prejudgment interest.

C. Standards Applicable to Post Verdict Motions

1. Judgment as a Matter of Law

On an issue tried to a jury, judgment as a matter of law may be entered only where "there is no legally sufficient evidentiary basis for a reasonable jury" to find for the nonmoving party on the issue. Fed. R. Civ. P. 50. The Supreme Court has explained:

> in entertaining a motion for judgment as a matter of law, the court should review all of the evidence in the record. In doing so, however, the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence. *Lytle v. Household Mfg., Inc.*, 494 U.S. 545, 554-55 (1990); *Liberty Lobby, Inc.*, [477 U.S. 242, 254 (1986)]; *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 696, n.6 (1962). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Liberty Lobby*, *supra*, at 255. Thus, although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe.

Reeves v. Sanderson Plumbing Products, Inc., 530 U.S. 133, 150-51 (2000).

In addressing St. Jude's motions for judgment as a matter of law, the court reviews the evidence in the light most favorable to CPI, granting CPI every reasonable inference that the jury might have drawn in its favor. *See SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1354-55 (Fed. Cir. 2000) (reversing denial of judgment as a matter of law); *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1357-58 (Fed. Cir. 1999) (affirming denial of judgment as a matter of law).

The court may set aside the jury's verdict and enter judgment as a matter of law only when the evidence is such that, without resolving conflicts in the testimony or otherwise considering the weight of the evidence, there can be but one conclusion as to the verdict that reasonable jurors could have reached. *SIBIA Neurosciences*, 225 F.3d at 1355; *Lane v. Hardee's Food Systems, Inc.*, 184 F.3d 705, 706-07 (7th Cir. 1999); *Klunk v. County of St. Joseph*, 170 F.3d 772, 775 (7th Cir.1999).

2. Motions for New Trial

The Federal Circuit treats the standard for granting a new trial as a procedural issue governed by regional circuit law. *E.g., Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1374 (Fed. Cir. 2001). Under Seventh Circuit law, in deciding both sides' motions under Rule 59 of the Federal Rules of Civil Procedure seeking a new trial on various issues, the court must determine whether the jury's verdict was against the weight of the evidence, whether the damages were excessive, or whether for other reasons the trial was unfair. *Westchester Fire Ins. Co. v. General Star Indemnity Co.*, 183 F.3d 578, 582 (7th Cir. 1999).

A party seeking to establish the need for a new trial based on the weight of the evidence must carry a substantial

burden, which the Seventh Circuit has phrased in different ways. A district court may grant a new trial because the verdict was against the weight of the evidence "only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks [the court's] conscience." *Latino v. Kaizer*, 58 F.3d 310, 315 (7th Cir. 1995) (finding abuse of discretion in district court's decision to grant a new trial based on weight of evidence; trial judge improperly usurped the jury's role in deciding the most reasonable inferences to be drawn from the evidence); *accord*, *Cefalu v. Village of Elk Grove*, 211 F.3d 416, 424 (7th Cir. 2000) ("Only when a verdict is contrary to the manifest weight of the evidence should a motion for a new trial challenging the jury's assessment of the facts carry the day.").

II. '472 Invalidity--The Written Description Requirement

The '472 patent claims an "implantable externally programmable cardioverting device" (Claim 1) and a related method for "electrically cardioverting a heart" (Claim 18). St. Jude contends that Claims 1 and 18 of the '472 patent are invalid for failure to comply with the written description requirement of 35 U.S.C. § 112 ¶ 1. The written description in the '472 patent describes two manually operated devices, one operated by the patient and the other by a physician. The implanted devices operate when either the patient or a physician diagnoses an arrhythmia and then activates the device to deliver an electrical charge to the heart.

The '472 claims are not limited to devices and methods for treating atrial arrhythmias. They also reach devices and methods for treating ventricular arrhythmias. Notwithstanding the broad terms of the '472 patent claims, the explicit terms of the '472 patent description are limited to devices and methods for treating only atrial arrhythmias, not ventricular arrhythmias. Despite these limits, CPI contends that

the '472 patent implicitly describes a device and method suitable for treating some ventricular arrhythmias, and that a person of ordinary skill in the art would have recognized that the description extended to ventricular devices and methods.

The jury rejected St. Jude's written description defense. St. Jude has renewed its motion for judgment as a matter of law and has moved in the alternative for a new trial on the defense.[2]

The court finds as a matter of law that Claims 1 and 18 of the '472 patent are invalid for failure to comply with the written description requirement. In the alternative, the court grants a new trial on the issue because the overwhelming weight of the evidence on this defense favored St. Jude. Failure to grant a new trial on the issue would result in a miscarriage of justice. The '472 description does not convey, either expressly or inherently, that the inventors were in possession of a device or method for the treatment of ventricular arrhythmias, as the '472 patent claims.

A. The Court's Claim Construction

The written description issue must be understood against the background of the court's claim construction. St. Jude argued (and still contends) that Claims 1 and 18 of the '472 patent should be limited to a device and method for treating only atrial arrhythmias, not ventricular arrhythmias, which are far more dangerous and which call for automatic rather than manually operated implantable devices. St. Jude built that argument on several pillars. The '472 specification repeatedly refers only to atrial conditions. The prosecution history shows that the inventors and their attorney emphasized

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[2] The written description issue is briefed in Docket Nos. 813, 843, and 867.

the difference between the atrial conditions and treatments addressed by their invention, and ventricular conditions and treatments. The inventors and their attorney emphasized that difference in distinguishing prior art for ventricular devices.

The court found, however, that the plain language of the claims—referring without limitation to "heart" and "cardioverting" device—indicated "an intentional choice by the patentee to reach beyond the embodiments discussed in the specification." Entry on Claim Construction at 12, *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 2000 WL 1765358, at * 6 (S.D. Ind. Nov. 29, 2000); *see also, e.g., Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1302-03 (Fed. Cir. 1997) (one of many cases cautioning against limiting scope of claim to the preferred embodiment or specific examples in the specification). In adopting this broad construction, the plain language of the claims was the dominant consideration. The court recognized that the broad language of the claims raised validity issues, but those issues were left for later resolution. Entry on Claim Construction at 18, 2000 WL 1765358, at *10.

B. The Written Description Requirement

The validity issue arises under the written description requirement of 35 U.S.C. § 112 ¶ 1. The patent specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...."

Most relevant here: "The purpose of this provision is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345-46 (Fed. Cir. 2000); *accord, Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991) ("Adequate de-

scription of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.") (citation omitted).

To satisfy the written description requirement, the disclosure must convey with reasonable clarity to persons of ordinary skill in the art that the inventor was in possession of the claimed invention. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323-24 (Fed. Cir. 2000); *Vas-Cath*, 935 F.2d at 1562-63. It is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure .... Rather, it is a question whether the application necessarily discloses that particular device." *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (emphasis in original) (citation omitted), *superseded by rule on other grounds as explained in Kubota v. Shibuya*, 999 F.2d 517, 521 (Fed. Cir. 1993).

The applicant does not need to describe exactly the subject matter claimed. *Vas-Cath*, 935 F.2d at 1563. Missing descriptive matter may be present "inherently" in a specification where persons of ordinary skill in the art would recognize it upon reviewing the specification. *See Reiffin*, 214 F.3d at 1346, citing *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

As in many written description cases, *see Vas-Cath*, 935 F.2d at 1560, the issue arises here because the '472 patent sought the benefit of an earlier filing date of an earlier application. The '472 patent issued from a continuation application filed on August 9, 1979, that derived from an earlier "grandparent" application filed on April 25, 1974. *See* Ex. 1824 (Serial No. 464,180). The two applications share an essentially identical specification. The issue is whether that specification adequately supports the claims of the continuation application that issued as the '472 patent.

Compliance with the written description requirement is a question of fact. *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995); *Vas-Cath*, 935 F.2d at 1563. In addition, invalidity on this basis must be proved by clear and convincing evidence. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376-77 (Fed. Cir. 2001). The court turns to the evidence at trial.

C. Atrial Arrhythmias and Ventricular Arrhythmias

Arrhythmias are generally classified by the type of arrhythmia and by the location in the heart. The seriousness of different arrhythmias and the needs for treatment vary dramatically.

For purposes of the written description issue, it is sufficient to distinguish between two types of arrhythmias—tachycardia and fibrillation. Tachycardia is a fast but regular heart rate. Fibrillation occurs when the heart beats in a disorganized, chaotic fashion due to unregulated electrical activity in the heart.

Both tachycardia and fibrillation can occur in either the atria (the two upper "collecting" chambers of the heart) or in the ventricles (the two lower "pumping" chambers of the heart).

Atrial arrhythmias, both tachycardia and fibrillation, are generally not life-threatening. They are typically accompanied by only mild symptoms. Treatment may be elective and need not be administered immediately. As Dr. Mirowski told the Patent & Trademark Office (PTO): "The wearer [of the implantable device] is able to recognize when he is experiencing atrial fibrillation; and he, himself, can initiate a defibrillating procedure. Or, if he chooses, the individual can consult with his physician, discuss his suspected arrhythmia, and decide either to, or not to, initiate a defibrillating proce-

dure." Ex. 4053 at 4053.83 (Mirowski Declaration ¶ 11, dated June 8, 1977).[3]

Ventricular arrhythmias are very different. Ventricular fibrillation prevents effective pumping of blood to the brain and other organs. A person suffering ventricular fibrillation loses consciousness in a matter of seconds. If the condition is not treated successfully within a few minutes, the unconscious person will die. Thus, an implantable device designed to treat patients who experience ventricular fibrillation must automatically detect and treat the condition so that a shock will be delivered even if the patient loses consciousness (at least assuming that the patient is not permanently living in a hospital and being monitored where external devices and medical staff are always nearby).

Ventricular tachycardia is dangerous but not always as immediately lethal as fibrillation. CPI's expert Dr. Prystowsky testified that ventricular tachycardias "can come in all shapes and sizes. Some are clearly life threatening and if you don't treat them immediately, you're dead." Tr. 126. Some ventricular tachycardias are "potentially lethal" but others are not. Tr. 127. Dr. Prystowsky described the testing procedure for ICDs for patients with ventricular tachycardia, in which the cardiologist uses electrical shocks to induce the arrhythmia and then uses the ICD to correct it. Even a patient with a stable ventricular tachycardia can deteriorate to an unstable, potentially lethal, arrhythmia without warning, so the ICD must be tested to ensure it can perform defibrillation. Tr. 140-42.

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[3] CPI offered evidence that it is possible in rare cases for a patient to collapse or to lose consciousness from atrial fibrillation. Tr. 179.

To avoid the written description defense, CPI has devoted a great deal of its brief to re-arguing the claim construction issue upon which it prevailed. But that victory is beside the point when it comes to evaluating whether the written description will support claims as broad as those advocated by CPI.

The '472 patent's written description shows only two manually operable embodiments, one operated by a patient and the other by a physician. CPI, in its more specific arguments directed to evidence on the written description issue, agrees that the manually operated '472 invention is not at all suitable for treating ventricular fibrillation and at least the most dangerous types of ventricular tachycardia. CPI has built its case on Dr. Tacker's theory that there is a "special category" of ventricular tachycardia patients who suffer from only "benign" ventricular tachycardia. Tr. 232. Dr. Tacker acknowledged that ventricular tachycardia can deteriorate to ventricular fibrillation. Tr. 231. He also testified that, "in a particular patient, it may be very difficult, or even impossible to determine how dangerous the tachycardia is going to become." *Id.* But he testified that there is an "extreme example of a very benign tachycardia," one in which "the patient has never progressed to fibrillation" and cannot even be induced to fibrillation in electrophysiological testing. *Id.* For such a rare patient, Dr. Tacker testified, "it would not be dangerous for that patient to treat herself for ventricular tachycardia." Tr. 232. No other witness agreed with Dr. Tacker on this point, which is addressed in more detail below.[4]

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[4] Dr. Tacker testified that he believed a physician-operated, non-automatic cardioverting device could be used to treat "all of the tachyarrhythmias," including ventricular fibrillation. Tr. 232, 305-07. The court fully credits this testimony to the extent Dr. Tacker intended to suggest that a person of ordinary skill in the art would

[Footnote continued on next page]

D. Explicit Disclosures in the Patent's Written Description

The written description of the '472 patent refers explicitly and repeatedly to the treatment of atrial arrhythmias. It contains no explicit references anywhere to treatment of ventricular arrhythmias.

The Abstract of the patent identifies: "An externally controlled implantable electronic device for delivering a cardioverting pulse of energy to the atrium of an ailing heart." (All emphases in this section of the entry have been supplied by the court.) The Background section states:

> There are scores of individuals walking the streets today who experience recurring episodes of atrial fibrillation, atrial flutter, or tachycardia. While not life-threatening, these supra-ventricular [i.e., atrial] arrhythmias can

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recognize that it might be *possible* to adapt the disclosed physician-operated embodiment for the treatment of ventricular fibrillation in highly controlled settings where the patient is always near the physician. However, to the extent this testimony was intended to be an opinion that the written description of the '472 patent discloses that the inventors possessed an implantable ventricular defibrillator at the time of filing, the testimony simply does not comport with the legal standard for the written description requirement. *See Continental Can*, 948 F.2d at 1268-69 (stating that inherency "may not be established by probabilities or possibilities"). The '472 patent describes use of the device only in situations in which the patient recognizes an atrial arrhythmia and then either activates a device or visits a doctor to have it activated. Both scenarios are impossible for ventricular fibrillation.

> become debilitating and lead to complications, and hence require treatment when present.
>
> * * *
>
> It is toward the facilitation of treatment for and the reduction of the risks to those patients suffering from recurring episodes of atrial fibrillation, flutter and tachycardia that the present invention is directed.

'472 Patent, col. 1, *ll.* 12-17, 40-43.

The Summary of the Invention section begins with a similar statement: "The present invention relates to an *atrial* device designed to be implanted under the skin of patients who frequently suffer from bouts of *atrial* fibrillation, flutter or tachycardia." *Id.*, col. 1, *ll.* 46-49. The summary explains that in the embodiment of the invention designed for operation by a physician, the cardioverting energy is discharged through either "the test load or the implanted *atrial* catheter." *Id.*, col. 1, *l.* 60 to col. 2, *l.* 12. In the embodiment operated by the patient: "The patient who frequently undergoes attacks of *atrial* fibrillation, flutter or tachycardia can be taught to recognize the symptoms of such arrhythmias." *Id.*, col. 2, *ll.* 15-18.

References to atrial arrhythmias also appear in several statements of the objects of the invention, as well as in the Detailed Description of the Drawings. *See, e.g.*, *id.*, col. 4, *ll.* 51-59 (describing the drawing of the physician-operated embodiment shown in Figures 1 and 2; "The patient suffering from a convertible atrial arrhythmias [sic, arrhythmia], such as atrial fibrillation, flutter or tachycardia, is examined by the physician . . . ."); *id.*, col. 6, *ll.* 1-5 (stating that the energy stored on the capacitor can be discharged into a test load or fed directly into a catheter "implanted in or about the *atrium* "of a heart); *id.*, col. 7, *ll.* 3-8 (describing the "totally implantable embodiment of the invention elective *atrial* device"

diagramed in Figure 3). There are many more similar references to the atrial nature of the invention.

The '472 patent specification contains exactly zero references to ventricular arrhythmias. There are no explicit references to ventricular tachycardia. The written description also does not expressly suggest that the device could be modified to treat a ventricular arrhythmia. The only reference to the heart's ventricle that appears in the written description refers to the catheter that is implanted in the ventricle to generate an ECG signal that is sent from the heart to the device. *See*, *e.g.*, *id.*, col. 8, *ll.* 36-39.

In light of the numerous express references to the invention as an atrial device designed to treat atrial arrhythmias and absence of any express references to ventricular arrhythmias, the court agrees with St. Jude that the written description of the '472 patent does not expressly disclose a device for treating ventricular as well as atrial arrhythmias. Even applying the clear and convincing standard, no reasonable jury could reach the opposite conclusion.

E. CPI's Inherent Disclosure Theory

As noted, the applicant need not describe exactly the subject matter claimed. Descriptive matter may be present inherently where persons of ordinary skill in the relevant art would recognize it upon reviewing the specification. *See Reiffin*, 214 F.3d at 1346. For the missing limitations to be inherent in the disclosure, however, the missing descriptive matter must be necessarily present in the structure described. *See Continental Can*, 948 F.2d at 1268-69 (stating that inherency "may not be established by probabilities or possibilities"). Further, the written description requirement is not satisfied if the disclosure "would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

CPI presented some evidence in an effort to show that the written description of the '472 patent discloses that the inventors were in possession of the claimed ventricular invention at the relevant time. Dr. Tacker, an M.D./Ph.D. and person of at least ordinary skill in the art of implantable cardioverting devices, testified that he understood the written description of the '472 patent to support the claims that reach ventricular cardioversion. He supported that opinion with three reasons.

First, he stated that the representation of the ECG signal shown in Figure 2 of the patent (which depicts the physician control panel that is used in conjunction with the implantable unit shown in Figure 1) is characteristic of a ventricular tachycardia. When asked to explain this opinion, Dr. Tacker purported to diagnose the arrhythmia from this tiny sketch. Tr. 234-36. The court was so incredulous in response to this testimony that, when it seemed CPI's counsel had tried to put words in Dr. Tacker's mouth, the court intervened to clarify whether Dr. Tacker actually professed to hold such a view. To the court's amazement, Dr. Tacker then answered: "Yes, it is my view that 44 [the drawn ECG signal] is a depiction of ventricular tachycardia." Tr. 236. Figure 2 is shown below at page 43.

This testimony was absurd on its face. It is not sufficient to avoid judgment as a matter of law. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159-60 (Fed. Cir. 1998) (reversing denial of judgment as matter of law on written description defense where patentee relied on expert to claim that required description was "inherent" in specification); *see also Augustine Medical, Inc. v. Gaymar Industries, Inc.*, 181 F.3d 1291, 1303 (Fed. Cir. 1999) (affirming summary judgment on written description issue despite expert's assertion that claimed invention was inherent in specification). As the Federal Circuit said in *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, a jury finding will be left undisturbed

if it is based on substantial evidence—evidence that would allow a reasonable jury to find as it did—but a "mere scintilla" is not enough. 225 F.3d 1349, 1354-55 (Fed. Cir. 2000) (reversing denial of judgment as a matter of law on obviousness).

Despite Dr. Tacker's testimony, the specification itself describes the drawing 44 as the ECG signal of a "patient suffering from a convertible *atrial* arrhythmia, such as *atrial* fibrillation, flutter or tachycardia." '472 Patent, col. 4, *ll.* 53-66 (emphasis added). Confronted with this problem, Dr. Tacker conceded there was "a mismatch here" between the specification and (his view of) the drawing. Tr. 291. Dr. Tacker also admitted that even a drawing of an ECG signal for atrial arrhythmias would show the largest spikes or deflections for the ventricular contractions. Tr. 286.[5] The fact

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[5] The absurdity of this testimony also comes through in Dr. Tacker's cross-examination leading up to the concession cited in the text:

> Q Now, even if a patient has an atrial arrhythmia, the largest spikes that will be seen on the monitor come from the ventricles, isn't that right?
>
> A In a broad sense that is true, but I can't say that it is always true, because if there were no ventricular beats at all in a patient with atrial fibrillation, then the atrial would be the largest one could see.
>
> Q Let's assume the patient is alive and his ventricles are beating.
>
> A No, no, if a fairly long period of time there were no ventricular R waves and that patient had atrial fibrillation, this is not common, but it can occur. But just trying to be thorough here.

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that the small not-to-scale drawing does not show diagnosable details of the atrial contractions cannot support a reasonable opinion that the drawing reflects a ventricular tachycardia that is mentioned nowhere in the specification.[6]

Second, Dr. Tacker noted that the rotary dial shown as element 36 on Figure 2 appears to be set at about seventeen. Tr. 236-37. The written description explains that the rotary dial is used to select the amount of energy for cardioversion. After implicitly assuming that the units shown on the drawing of the rotary dial reflect whole joules (wattseconds), Dr. Tacker further explained that a cardioverting shock of seventeen joules was within the range of energy that is typically used to treat a ventricular tachycardia. *Id.* at 237. Taking the ECG display and the rotary dial shown in Figure 2 together, Dr. Tacker testified that the drawing depicted ventricular tachycardia. *Id.* at 235-37.

Nothing in the detailed description of Figure 2 provides any basis for Dr. Tacker's interpretation of the drawing. The

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Tr. 285-86. There is of course no suggestion in the specification of any such rare occurrence. One hopes that any medical attention in such a case would be focused on the deadly absence of ventricular activity.

6 The Federal Circuit has explained that even a written description that renders a claimed invention "obvious" may not be sufficient to satisfy the written description requirement of § 112 ¶ 1, and that "a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, ¶ 1." *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (affirming Eli Lilly's written description defense).

written description actually suggests that Dr. Tacker's interpretation of Figure 2 is wrong. *See, e.g.*, '472 Patent, col. 1, *ll.* 50-59 (describing the invention as involving cardioversion via an "intraatrial catheter" that "has been shown to require energies of five watt-seconds or less"); *id.*, col. 4, *ll.* 51-56 (describing the drawing of the physician-operated embodiment shown in Figures 1 and 2; "The patient suffering from a convertible atrial arrhythmias [sic, arrhythmia], such as atrial fibrillation, flutter or tachycardia, is examined by the physician, preferably with the aid of ECG equipment.").

Whatever the drawings of the ECG signal and the rotary dial actually depict, as a matter of law it is unreasonable to rely on the drawings in the manner suggested by Dr. Tacker's testimony. Figure 2 is a pictorial representation of the physician console. It is not, and was not intended to be, a realistic, scaled rendering of the console as a whole or of the ECG signal or the rotary dial in particular. If the drawing is to be believed, the display shows a cardioverting energy pulse (46), yet the power switch on the device is turned off! Dr. Tacker's testimony concerning Figure 2 is not substantial evidence upon which a jury could reasonably rely to find support for implicit disclosure of a ventricular device.

The third basis for Dr. Tacker's opinion that the written description of the '472 patent implicitly but adequately discloses the claim to a ventricular invention was that there are generic references to "cardioversion" and the "heart" in the specification that are not qualified by the term "atrial." Tr. 239-42. Dr. Tacker found the following sequence from the list of objects of the invention to be particularly revealing:

> Still a further object of the present invention is to provide a device which will enable the cardioversion of a heart undergoing *atrial fibrillation, flutter or tachycardia*, without the intervention of a physician.

> Additional objects of the present invention are to provide an implanted device whose operation is capable of being verified before discharge into the heart, whose discharge is capable of being synchronized with the QRS complex, *in which the energy level of the discharge can be manually programmed or automatically increased in successive attempts at cardioversion*, and whose discharges can be monitored from external to the skin of the patient.
>
> Yet another object of the present invention is to provide a method for cardioverting a heart suffering from *an atrial malfunctioning, wherein cardioversion is initiated* by a physician or by the wearer while in a state of consciousness, and wherein cardioversion is accomplished by an implanted electronic device manually triggered from external to the skin of the wearer.

'472 Patent, col. 3, *ll.* 5-25 (emphasis added).

Dr. Tacker pointed out that the second of the three paragraphs quoted above (identifying "additional objects of the present invention") refers broadly to "cardioversion" and the "heart." Tr. 241. The first and third paragraphs expressly refer to "atrial" arrhythmias. According to Dr. Tacker, the omission of any reference to "atrial" arrhythmias in the middle paragraph shows that the aspects of the invention listed in the middle paragraph, including programmable energy levels, were intended to have a broader application. Tr. 242.

The word choice in these paragraphs adds nothing substantial to CPI's argument for inherent disclosure. Even the statement of "additional objects of the present invention" emphasized by Dr. Tacker refers to "the present invention," which was expressly defined two columns earlier as an

"atrial device." With the mountain of references to atrial arrhythmias that appear in the written description and no further basis for the inference drawn by Dr. Tacker, it would be unreasonable to conclude that, when reciting the objects of the invention, the patentees intentionally drew such an important distinction (*i.e.*, the distinction between atrial cardioverters and cardioverters that also treat ventricular arrhythmias) in such a subtle and indirect manner.[7]

Next, CPI contends that a reasonable jury could find that the written description of the '472 patent inherently supports the inventions defined in Claim 1 and Claim 18 based on Dr. Tacker's testimony that there is a subset of "benign" or "stable" ventricular tachycardias that could be treated with a non-automatic cardioverter that is similar to those disclosed in the patent. The argument is that a person of ordinary skill in the art would necessarily recognize such a disclosure by reading the patent specification.

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[7] Cross-examination of Dr. Tacker showed exceptions to his interpretive principle that unqualified references to terms like "heart," "arrhythmia," or "cardioversion" indicate treatment of the atria or the ventricles. *See* Tr. 308-11 (cross examination discussing the generic, unqualified references to terms such as "heart" and "fibrillation" at column 8, lines 13-15 & 44-49). Dr. Tacker explained the passages by clarifying that the proper interpretation of the terms "[d]epends upon the context." Tr. 309. The court agrees that terms need to be read in context. However, nothing in the context of the '472 patent's written description indicates disclosure of a ventricular device. The fact that Dr. Tacker's interpretive principle cannot be applied consistently is another reason that his emphasis on pregnant omissions falls well short of being substantial evidence that the written description of the '472 patent supports its broad claims.

For purposes of deciding defendants' motion for judgment as a matter of law, the court fully credits Dr. Tacker's testimony that some very stable ventricular tachycardias can be treated using a non-automatic device.[8] Even accepting this testimony as true, a reasonable jury could not find that a device and method for treating stable ventricular tachycardias are inherently disclosed in the written description of the '472 patent.

Dr. Tacker himself testified that ventricular fibrillation and some ventricular tachycardias are potentially lethal. *See* Tr. 315, 317. Dr. Tacker also agreed that many patients with non-life threatening ventricular tachycardia should be treated as though their conditions were life-threatening because of the risk that the condition might deteriorate. *See id.* at 308, 314, 316. As a result, Dr. Tacker had to set forth carefully the special conditions under which he would consider it possible to treat ventricular arrhythmias using a non-automatic device.

Essentially, Dr. Tacker testified that if the patient were not in a highly controlled hospital environment, where all of the resources for dealing with an emergency would be available, the usefulness of a non-automatic device would be limited to patients fitting the "special case" of benign tachycardia. *See* Tr. 306, 307, 311, 313, 314. However, "the great number of patients have to be treated very conservatively" and would not be suited for a non-automatic device. Tr. 314; *see also* Tr. 306, 307, 311, 313-16. The disclosure contained

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[8] During his deposition, however, Dr. Tacker testified quite plainly that automatic detection means were required to treat both ventricular fibrillation and ventricular tachycardia. *See* Tr. 328-29. When confronted at trial with this flatly inconsistent testimony, Dr. Tacker said "that is not what I intended." Tr. 329.

in the written description of the '472 patent, in contrast, in no way suggests a narrowly circumscribed application of the invention to the treatment of "stable" ventricular tachycardias.

At the time of the filing of the '472 patent—which was prior to the first human implant of an ICD—a person of ordinary skill in the art would not have been able to divine from the specification the limits of the device as applied to ventricular tachycardias. As shown by the testimony in this case, experts in the field continue to disagree about the practical application of a non-automatic device to treat any ventricular arrhythmias. Even when the evidence is viewed in the light reasonably most favorable to CPI, so that the court assumes it would have been possible to use the disclosed embodiments to treat some very unusual patients' ventricular arrhythmias, it was outright dangerous to use the inventions for other patients, as CPI's witnesses agreed. Under those circumstances, the inventors could not show the required "possession" of a ventricular device without saying something about where they envisioned drawing the literally vital line.

Tacker and CPI also relied on two implantable devices manufactured by Medtronic and Intermedics that treated ventricular tachycardia without automatic defibrillation backup. Tr. 243-44. Neither device was invented until well after the '472 patent application, and neither provides support for finding that a person of ordinary skill in the art would have divined from the '472 specification that the inventors possessed in 1974 a device for manual treatment of ventricular tachycardia.

Tacker and CPI also rely on a 1996 article describing a patient who was, in the medical language, "a cooperative, insightful patient" for whom a manually operated device to treat ventricular tachycardia was found to be useful. Ex. 1856; *see* Tr. 244-45 (Tacker). Dr. Tacker later weakened his testimony by saying that this 1996 article showed only an

example of using a manually operated implantable device for ventricular tachycardia. Tr. 317, 319. For purposes of the written description requirement, the relevant time is the time of the patent application in 1974. *See Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (to take advantage of earlier application date, "the prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought").

The article itself undermines CPI's and Dr. Tacker's reliance on it to show what a person of ordinary skill in the art would have understood from the description in 1974. The authors of the 1996 article wrote: "We describe here *for the first time* the use of a magnet for patient-enabled detection and termination of ventricular tachycardia." Ex. 1856 at 3 (emphasis added). What was being described for the first time in 1996 adds nothing to what the inventors were required to disclose in 1974 in order to obtain the benefit of the 1974 filing date.

In drafting their original disclosure in 1974, the applicants for the '472 patent chose to draw a line at the cardioversion of atrial arrhythmias. Their reasons for limiting their disclosure in this manner are not material here in determining whether they complied with the written description requirement when they made the later and broader claims to the entire heart in the '472 patent. There are numerous explicit references to the atrial arrhythmias that the disclosed non-automatic devices were designed to treat through cardioversion. Nothing in the patent specification "necessarily" discloses that any class of ventricular tachycardia (benign, stable, or otherwise) could be treated using the disclosed devices. Nonetheless, in pursuing the later '472 patent, the in-

ventors relied on their original disclosure to support much broader claims. In doing do, the inventors overreached.[9]

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[9] To emphasize the undisputed fact that persons of ordinary skill in the art, as well as the inventors themselves, found the distinction between atrial arrhythmias and lethal ventricular arrhythmias highly relevant, St. Jude introduced several statements from the prosecution history of patent applications in the same chain of applications to which the '472 patent belongs. The attorney for the inventors told the PTO the following: The atrial arrhythmias described above are not to be confused with ventricular arrhythmias such as ventricular fibrillation or ventricular tachycardia. At the onset of such an arrhythmia, the patient might feel a slight sensation of dizziness. Unconsciousness would result within ten to fifteen seconds, and if left untreated, death would occur within a matter of minutes. *The inventive patient-operated cardioverting device would have no use to an individual undergoing ventricular tachycardia or ventricular fibrillation.*

Trial Ex. 4055 at 4055.58 (remarks supporting an amendment to the claims and specification in patent application Serial No. 464,180, dated March 17, 1975) (emphasis added). (This same statement by the attorney also appears in Ex. 1824 at 1824.70. Witnesses sometimes referred to that exhibit. *See* Tr. 637 (Mower).) *See also* Ex. 4053 at 4053.77-78 (response to patent examiner, dated June 22, 1977) (person of ordinary skill in the art would not have considered a non-automatic approach to ventricular defibrillation, and ventricular and atrial defibrillation had evolved into "two distinct areas of technology"); Ex. 4053 at 4053.83-84 & 4053.86 (declarations of Dr. Mirowski and Dr. Mower dated June 8, 1977 distinguishing between atrial and ventricular conditions and devices, with Dr. Mower stating "an implantable non-automatic ventricular defibrillator is unrealistic and totally impractical"). Both Dr. Tacker and Dr. Mower tried to walk away from the attorney's clear declaration that the invented

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A person of ordinary skill in the art reading the specification would have been left to speculate as to the modifications of the disclosed atrial embodiments that the inventors had in mind when they claimed the right to exclude others from practicing any cardioverting device having the limitations recited in the claims. As a result, the court finds defendants are entitled to judgment as a matter of law that the inventors' leap from the written description of work on atrial devices to the broader "cardioverting" device and method claimed in the '472 patent is not inherently supported by the written description.

Because the written description of the '472 patent does not adequately support the extension of Claim 1 and Claim 18 to a ventricular device or method, either explicitly or inherently, a jury could not reasonably find that the defendants failed to prove their written description defense by clear and convincing evidence. As a result, Claims 1 and 18 of the

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device "would have no use to an individual undergoing ventricular tachycardia." Tr. 325 (Tacker); 637 (Mower) ("I think he misspoke and that it should have been malignant or lethal ventricular tachycardia."). *Cf. Tyler Refrigeration v. Kysor Industrial Corp.*, 777 F.2d 687, 690 (Fed. Cir.1985) (attorney's admission alone provided clear and convincing evidence to support finding of invalidity for anticipation). In any event, these statements must be approached with caution. The statements were not made in support of the claims in the '472 patent. Instead, they relate to earlier claims (albeit claims drawn to the common original application from 1974) that were either abandoned or issued as separate patents. Nevertheless, these statements are part of the public record available for evaluating the '472 patent, and they describe the same specification.

'472 patent are invalid under the written description requirement of § 112 ¶ 1. In the alternative, because the weight of evidence on this issue at trial was so overwhelming, St. Jude is entitled to a conditional new trial on the defense in order to avoid a miscarriage of justice.

III. '472 Invalidity—Double Patenting

St. Jude asserts that Claims 1 and 18 of the '472 patent are also invalid for obviousness-type double patenting when compared to Claim 3 of U.S. Patent No. 3,952,750 (the '750 patent), which was issued to the same inventors based on the same specification. The doctrine of obviousness-type double patenting prohibits a patentee from "obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). Because all issued patents carry a presumption of validity, St. Jude bore the burden of proving its double patenting defenses by clear and convincing evidence. *See* 35 U.S.C. § 282.

In general, the issue of obviousness-type double patenting involves a two-step analysis:

> First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326, 52 U.S.P.Q.2d 1590, 1593 (Fed. Cir. 1999). Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. *Id.* at 1327, 195 F.3d 1322, 52 U.S.P.Q.2d at 1595. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. *In re Berg*, 140 F.3d 1428, 1431, 46

> U.S.P.Q.2d 1226, 1229 (Fed. Cir. 1998). A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.

See Eli Lilly, 251 F.3d at 968 (footnote omitted).

Procedurally, St. Jude has presented the double patenting defense in terms of both a renewed motion for judgment as a matter of law and a request for the court's own findings on the issue, treating the jury's adverse verdict on this defense as only advisory.[10] Is the issue of obviousness-type double patenting as presented in this case an issue of law for the court, as St. Jude argued, or of fact for the jury, as CPI argued? During the trial, the court deferred a decision on that question. The court submitted the defense to the jury and postponed until after the trial a decision on whether the jury's verdict should be deemed advisory or not. Ultimately, however, that question need not be resolved. Under any applicable standard, St. Jude established its double patenting defense as a matter of law, based solely on the two patents themselves. No additional factual material need be considered.[11]

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[10] The double patenting issue is briefed in Docket Nos. 814, 854, and 868.

[11] CPI argued at trial that the jury would need to consider the so-called *Graham* factors on obviousness. Those arguments led the court to require the jury to sit through the defendants' evidentiary presentation on this rather arcane issue. However, neither CPI nor St. Jude presented any evidence on the *Graham* factors. CPI also has not shown that the double patenting issue turns on any factual considerations outside the scope of the two patent documents.

A. The Common Background of the '472 Patent and the '750 Patent

The two commonly owned patents at issue in this case are the '472 patent and the '750 patent. The '750 patent was issued on April 27, 1976. The ' 472 patent was issued on February 23, 1982. The '750 patent expired in 1993, before the period of infringement of the '472 patent alleged by plaintiffs in this case.

The '750 patent and the '472 patent both claim cardioverting devices and methods for using those devices. Although the two patents were issued almost six years apart, they are closely related. The application that resulted in the '472 patent was a continuation of an abandoned application, which was itself a continuation of the application that had resulted in the '750 patent. By virtue of that relationship, the two patents share a common written description and a common effective filing date of April 25, 1974. Each patent's specification discloses the same two manually operated embodiments. One embodiment is a patient-operated cardioverting device. The other embodiment is a physician-operated cardioverting device.

B. Claim 3 of the '750 Patent and Claim 1 of the '472 Patent

St. Jude asserts a fairly narrow application of the obviousness-type double patenting doctrine. St. Jude contends that each limitation recited in Claim 1 of the '472 patent has a corresponding limitation in Claim 3 of the '750 patent that is either identical or in a species/genus relationship. To resolve the issue, the court must construe the claim in the earlier '750 patent and the claim in the later '472 patent. The court must then determine whether, as a matter of law, a device that infringes Claim 3 of the '750 patent would necessar-

ily infringe Claim 1 of the '472 patent due to a complete overlap of the '472 Claim 1 limitations.[12]

Claim 3 of the '750 patent is dependent on Claim 1 of the '750 patent. Rewritten in independent form, and with clauses separated for (relative) ease of reading, Claim 3 recites:

> An implantable non-automatic cardioverting device for delivering cardioverting shocks to the heart of a wearer whose atrium requires cardioversion, said device being controlled directly by the wearer from external to the skin of the wearer, and comprising:
>
> storage means for storing an amount of energy for converting an abnormal supra-ventricular cardiac rhythm to normal sinus rhythm;
>
> delivery electrode means associating said storage means with the atrium of the wearer and for discharging the stored energy into the atrium;

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[12] This framework for analysis would not be appropriate in all cases involving an issue of obviousness-type double patenting. *See, e.g., Eli Lilly*, 251 F.3d at 968 n.6 ("An absence of overlap between the later claim and the earlier claim does not preclude a conclusion that the later claim is patentably indistinct from the earlier claim."); *In re Lonardo*, 119 F.3d 960, 967 (Fed. Cir. 1997) (claims held unpatentable on the ground of obviousness-type double patenting, "not because one could not practice the invention of the '762 patent without infringing claims 9 and 10, but because each of the additional limitations argued by Restorative Care is an obvious modification of the device defined in the '762 claim").

switch means for controlling the discharge of the stored energy into the atrium;

charging means for delivering to said storage means said amount of energy for converting such abnormal supra-ventricular cardiac rhythm;

receiver means for receiving commands from external to the skin of the wearer, for controlling the operation of said switch means, and for initiating the discharge of cardioverting energy into the atrium of the wearer in response to such commands;

non-implantable portable actuating means for issuing said commands said actuating means being manually operated by said wearer upon said wearer's sensing of a condition requiring cardioversion of the atrium;

command means for issuing a control signal for controlling the amount of energy which said charging means delivers to said storage means;

means for limiting the amount of energy which said charging means delivers to said storage means in accordance with said control signal;

means in said receiver means for receiving said control signals;

comparator means for comparing a signal indicative of the amount of energy stored by said storage means with a signal representative of said control signal; and

means for disabling said charging means once said storage means has stored the amount of energy indicated by said control signal

wherein said control signal is a serial binary control word; and further comprising

a control register for converting said serial binary control word into a parallel binary control word; and

a digital-to-analog converter for converting said parallel binary control word into a corresponding analog signal, said analog signal being said signal representative of said control signal.

'750 Patent, col. 8, *l.* 59 to col. 9, *l.* 25, and col. 9, *ll.* 31-38.

Claim 1 of the '472 patent claims:

In a cardioverting device, comprising:

storage means for storing energy to convert an abnormal cardiac rhythm to a normal sinus rhythm,

delivery electrode means for discharging the stored energy into the heart of a wearer of the device, and

switch means for controlling the discharge of the stored energy into the heart of the wearer,

said device further comprising charging means for deliverying [sic] to said storage means said energy to convert said abnormal cardiac rhythm,

determining means for determining when the stored energy has reached a predetermined magnitude for converting said abnormal cardiac rhythm, and

initiating means for initiating the discharge of converting energy into the heart of the wearer after the stored energy has reached said predetermined magnitude;

> the improvement wherein said device is an implantable externally programmable cardioverting device, and includes receiving means for receiving commands from external to the skin of the wearer of the device, said programming commands designating a predetermined magnitude of stored energy for converting said abnormal cardiac rhythm, said device also including selecting means responsive to said programming commands received by said receiving means for selecting said predetermined magnitude of stored energy, for converting said abnormal cardiac rhythm.

'472 Patent, col. 8 *l.* 64 to col. 9, *l.* 27.

C. Claim 3 of the '750 Patent as a "Hybrid" Claim

In construing Claim 3 of the earlier '750 patent, the court reaches two initial conclusions as a matter of law. First, Claim 3 of the '750 patent is a "hybrid" claim in the sense that the claim limitations recite some structures that are disclosed in the patient-operated embodiment (Figure 3 of both patents' specifications), and some structures that are disclosed in the physician-operated embodiment (Figures 1 and 2 of both patents' specifications). Second, Claim 3 of the '750 patent claims external programmability of the energy level to be used for cardioverting the heart. External programmability of energy levels is also the main "improvement" recited in Claim 1 of the '472 patent. The identical Figures 1, 2 and 3 of both patents are reproduced below.

[Figure 1 from '750 and '472 patents]

[Figures 2 and 3 from '750 and '472 patents]

To avoid the double patenting defense, CPI has argued that Claim 3 of the '750 patent relates only to the patient-operated embodiment, which does not include external pro-

grammability of energy levels. If that were true, then Claim 3 would not involve externally programmable energy levels.

Claim 3 of the '750 patent is a "hybrid" claim because it cannot be construed without reference to both of the embodiments disclosed in the patent specification. Some language in Claim 3 (drawn from independent Claim 1) tends to support CPI's argument that Claim 3 generally is directed to a patient-operated device. Nevertheless, several limitations in Claim 3 relate exclusively to the physician-operated embodiment and external programmability. Even CPI eventually conceded in its brief that Claim 3 is a hybrid claim, as the patent examiner found upon reexamination. *See* Docket No. 854 at 22, citing Trial Ex. 4054 at 4054.107. (To the extent that CPI argues that the claim is misconstrued if it does not read on either embodiment by itself, *see* Docket No. 854 at 3, CPI has only the inventors to blame. They created the confusion by choosing to rely on the earlier common application in order to gain the benefit of the earlier filing date.)

The limitations in Claim 3 that are drawn from the external programmability feature of the physician-operated embodiment generally involve the recited "control signals," which are received by a "receiver means." Specifically, Claim 3 recites a "receiver means for receiving commands from external to the skin of the wearer" and "command means for issuing a control signal for controlling the amount of energy which said charging means delivers to said storage means." These two limitations are then associated with one another by a third limitation which recites "means in *said receiver means* for receiving *said control signals*."

Thus, claim 3 of the '750 patent recites an implanted receiver means that receives control signals issued from external to the skin of the wearer, where the control signals serve the function of controlling the amount of energy to be used for cardioversion.

The patient-operated embodiment shown in Figure 3 does not include any structure that performs these functions of receiving control signals for controlling the amount of energy. In the patient-operated embodiment, the only external command or signal "received" by the implanted device is a magnetic field generated by a hand-held magnet 112 that the patient places over his chest when he senses a need for a cardioverting shock. The only structure affected by this magnetic field is a reed switch 114 that closes a circuit and turns the device on. The magnet and reed switch jointly serve as an on/off switch. As long as the magnet remains in place and the switch remains closed, the device runs through cycles of charging and discharging energy at increasing, but preset, energy levels. When the patient senses that the heart has returned to a normal rhythm, he removes the magnet, the switch opens, and the device stops charging and discharging. As CPI itself asserts, no structure disclosed in the patient-operated embodiment performs the function of receiving external signals that control the amount of energy to be used for cardioversion. *See* Docket No. 854 at 15 ("The Figure 3 device is not externally programmable.").

The dependent portion of Claim 3 expressly defines the "control signal" (which, per the limitations in independent Claim 1, is received from external to the skin of the wearer by means in the receiver means) as a "serial binary control word" that is converted into "a parallel binary control word," and that is further converted into an "analog signal . . . representative of said control signal." The disclosed magnet of the patient-operated device does not issue an externally-generated "control signal" in a "serial binary control word" format. Nor does the disclosed reed switch of the patient-operated device act as the "means in said receiver means" that receives a "control signal" in a "serial binary control word" format.

All of the disclosed structure that has anything to do with an externally-generated control signal in a "serial binary control word" format is found exclusively in the physician-operated embodiment in Figures 1 and 2. That disclosed structure is the structure that enables external programmability of energy levels as a feature of the physician-operated device, which is also the principal improvement claimed in the '472 patent. As explained in the '750 patent specification itself:

> When the rotary energy dial 38 [sic, should be 36] and the other controls on panel 20 are set by the physician, the operating control unit 20 provides, for example, a binary signal representative of the energy level to which the dial 36 is set .... This signal takes the form of a parallel binary control word.... The parallel binary control word ... is converted into a serial binary control word.... [T]he serial control word is ... sent to the implanted device along the information channel.
>
> * * *
>
> Then, when the load-data button 41 is depressed, the serial binary control word is transmitted along the information channel. The serial control word recovered by the receiver 18 takes the form of a timed set of pulses. The receiver 18 directs these serial pulses to a control register 48 which reconstructs them into their original parallel format. The parallel control word, along with other control information, provides a signal proportional to the desired energy level ....

'750 Patent, col. 5, *ll.* 3-34 (emphasis added).

Thus, the '750 patent specification shows as a matter of law that structures found exclusively in the physician-operated embodiment are disclosed structures that correspond to some of the means-plus-function limitations found in Claim 3 of the '750 patent—particularly including the "means in said receiver means for receiving said control signals." In addition, the supporting disclosure for all limitations in the dependent portion of Claim 3 can be found in the written description of the physician-operated device. As a result, even though the opening recitals of Claim 3 refer to an implantable non-automatic cardioverting device that is "controlled directly by the wearer," Claim 3 is in fact a "hybrid" claim that requires reference to both the patient-operated embodiment and the physician-operated embodiment, which both discloses and claims structures to provide externally programmable energy levels.

D. Comparing the Claims of the '472 and '750 Patents

The next step is to determine whether a device that infringes Claim 3 of the '750 patent necessarily infringes Claim 1 of the '472 patent. Under the narrow application of the obviousness-type double patenting doctrine that defendants have asserted in this case, the process of matching up limitations in the two claims presents continuing issues of claim construction. The court can and should decide those issues as a matter of law. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-89 (1996). That is, the defendants chose to rely strictly on the text of the claims to show that for each limitation in Claim 1 of the '472 patent there is either an identical corresponding limitation in Claim 3 of the '750 patent, or a narrower corresponding limitation in Claim 3 of the '750 patent that, as a matter of law, is in a species/genus relationship with the broader limitation from Claim 1 of the '472 patent.

CPI's brief on the double patenting issue is notable primarily for its obfuscation and stubbornness. Much of the obfuscation stems from (or perhaps seeks to take advantage of) the confusion created by the patentees' decision to use the earlier application for the '750 patent in order to take advantage of the earlier filing date. The court lays out in detail how each claim element in Claim 1 of the '472 patent was previously set forth or is a broader genus of a corresponding element in Claim 3 of the '750 patent.

Cardioverting Device: Claim 1 of the '472 patent begins: "In a cardioverting device, comprising. . . ." Claim 3 of the '750 patent includes: "An implantable non-automatic cardioverting device. . . ." The element of the '472 patent is a broader genus of the element of the '750 patent.

Storage Means: Claim 1 of the '472 patent includes: "storage means for storing energy to convert an abnormal cardiac rhythm to normal sinus rhythm." Claim 3 of the '750 patent includes: "storage means for storing an amount of energy for converting an abnormal supra-ventricular cardiac rhythm to normal sinus rhythm." In light of the court's construction of the '472 patent claims to include both atrial and ventricular cardioversion devices, this '472 element is also a broader genus of the element of the '750 patent.

Delivery Electrode Means: Claim 1 of the '472 patent includes: "delivery electrode means for discharging the stored energy into the heart of a wearer of the device." Claim 3 of the '750 patent includes: "delivery electrodes means associating said storage means with the atrium of the wearer and for discharging the stored energy into the atrium." The '472 language broadens the element to reach the entire heart, but the correspondence is plain.

Switch Means: Claim 1 of the '472 patent includes "switch means for controlling the discharge of the stored energy into the heart of the wearer." Claim 3 of the '750 patent includes: "switch means for controlling the discharge of the

stored energy into the atrium." The '472 language again broadens the element to reach the entire heart, and the correspondence is again plain.

Charging Means: Claim 1 of the '472 patent includes: "said device further comprising: charging means for delivering to said storage means said energy to convert said abnormal cardiac rhythm." Claim 3 of the '750 patent includes: "charging means for delivering to said storage means said amount of energy for converting such abnormal supraventricular cardiac rhythm." Again, the '472 language broadens the element to reach the entire heart, but the correspondence is plain.

Determining Means: Claim 1 of the '472 patent includes: "determining means for determining when the stored energy has reached a predetermined magnitude for converting said abnormal cardiac rhythm." This is a means-plus-function element under 35 U.S.C. § 112 ¶ 6 that requires identification of structure in the specification. The structure is described in column 6, lines 37-57 of the '472 patent, and it is depicted in Figure 1 as comparator 100 and input lines 106 and 110. Claim 3 of the '750 patent includes: "comparator means for comparing a signal indicative of the amount of energy stored by said storage means with a signal representative of said control signal. . . ." The comparator is item 100 in the identical Figure 1. It receives the signal along input line 106. These elements also match up between the two claims.

Initiating Means: Claim 1 of the '472 patent includes: "initiating means for initiating the discharge of converting energy into the heart of the wearer after the stored energy has reached said predetermined magnitude." The court has construed this element as a means-plus-function element for

which the structure is the manual discharge button 40 of Figure 2 and/or the AND gate 82 of the patient-operated embodiment in Figure 3.[13] Critical to the court's construction of this limitation was the requirement that the corresponding structure had to perform the initiating function "after the stored energy has reached said predetermined magnitude."

Claim 3 of the '750 patent includes: "receiver means for receiving commands from external to the skin of the wearer, for controlling the operation of said switch means, and for initiating the discharge of cardioverting energy into the atrium," and "non-implantable portable actuating means for issuing said commands," and "command means for issuing a control signal for controlling the amount of energy which said charging means delivers to said storage means." The corresponding structure in the '750 patent includes the manual discharge button 40 in the identical Figure 2 and the "load data button" 41 that issues the external control signal controlling the amount of energy to be stored for use in cardioversion. The fact that the '750 patent includes the additional limitation for manual operation using the "non-implantable portable actuating means" (i.e., the magnet 112 in Figure 3) does not affect the analysis. The '472 patent element is the genus broader than the species of the '750 patent element.

Receiving Means: Claim 1 of the '472 patent then includes: "the improvement wherein said device is an implantable externally programmable cardioverting device, and includes receiving means for receiving commands from external to the skin of the wearer of the device. . . ." The receiv-

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[13] CPI has argued all along that the "initiating means" includes the manual discharge button 40. St. Jude has consistently disagreed with this part of the court's claim construction.

ing means element is a mean-plus-function element. The corresponding structure is the receiver 18 in Figure 1.

Claim 3 of the '750 patent includes: "receiver means for receiving commands from external to the skin of the wearer," and "means in said receiver means for receiving said control signals." These are also means-plus-function elements. The corresponding structure includes the receiver 18 depicted in Figure 1. The "control signal" in Claim 3 is described as "controlling the amount of energy which said charging means delivers to said storage means" for cardioversion of the atria. Thus, Claim 3 necessarily claims a cardioversion device for which the energy levels are externally programmable, just as the device of Claim 1 of the '472 patent does.

To avoid this result, CPI argues that the "receiver means" of Claim 3 of the ' 750 patent is only the reed switch, which receives external commands from the "non-implantable portable actuating means." However, the reed switch and magnet of Figure 3 correspond to the "actuating means" in Claim 3 of the ' 750 patent. The "receiver means" of Claim 3 of the '750 patent must receive "said control signals," which control the amount of energy to discharged. The reed switch does not receive any control signal controlling the amount of energy to be used for cardioverting. The reed switch therefore is not the "receiver means" of Claim 3 of the '750 patent.[14]

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[14] Another reason the reed switch cannot be the "receiver means" of Claim 3 is that the reed switch does not "control the operation of said switch means," which refers to the discharge switch 85 in Figure 1 of the '750 patent. The discharge switch is controlled by the output of the AND gate 82, not the reed switch. The reed switch only *initiates* the charging of the storage element, the *discharge* of which is controlled by the AND gate 82. The reed

[Footnote continued on next page]

Programming Commands for Energy Levels: Claim 1 of the '472 patent includes: "said programming commands designating a predetermined magnitude of stored energy for converting said abnormal cardiac rhythm." Claim 3 of the '750 patent includes: "means for limiting the amount of energy which said charging means delivers to said storage means in accordance with said control signal," and "disabling said charging means once said storage means has stored the amount of energy indicated by said control signal." The "control signal" in the '750 patent is described as "controlling the amount of energy which said charging means delivers to said storage means" for cardioversion. Thus, the "control signal" in the '750 patent is the same as the "programming commands" of the '472 patent.

CPI has tried to support its position by focusing on the difference between the plural "said control signals" and the singular "control signal" in Claim 3 of the '750 patent. However, the *only* control signal identified in Claim 3 of the '750 patent is the "control signal for controlling the amount of energy which said charging means delivers to said storage means" for cardioverting the heart. There is no other control signal to which "said control signals" might be referring under CPI's theory.

CPI also contends that the "control signal" of the '750 patent is generated internally and is different from the "programming commands" of the '472 patent, which are received from external to the skin and which designate "a predeter-

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switch also cannot be the "receiver means" of Claim 3 because the reed switch does not "initiat[e] the discharge of cardioverting energy into the atrium of the wearer in response to such commands," as required by Claim 3.

mined magnitude of stored energy." However, the '750 patent does not require that the "command means" be part of the device implanted in the patient. The receiver means of the '750 patent receives "control signals" from outside the body, "external to the skin of the wearer." Claim 3 of the '750 patent requires only "command means for issuing a control signal for controlling the amount of energy which said charging means delivers to said storage means" for cardioverting the heart.

The only command means disclosed in the '750 patent that issue control signals for controlling the amount of energy are from the physician's console disclosed in Figures 1 and 2, which plainly shows a device with externally programmable energy levels for cardioversion. The command means of the '750 patent is a "means-plus-function" element subject to 35 U.S.C. § 112 ¶ 6. The '750 patent specification does not disclose any structure for "issuing a control signal for controlling the amount of energy which said charging means delivers to said storage means" other than the external console operated by the physician, as shown in Figures 1 and 2.

Contrary to CPI's argument, whether the actuating means are portable (as in the '750 patent) does not matter. The '472 patent does not specify whether such actuating means are portable or not, so its claim element is broader than the narrower '750 claim element. The difference therefore cannot avoid the double patenting defense.

Selecting Means: Finally, Claim 1 of the '472 patent includes: "said device also including selecting means responsive to said programming commands received by said receiving means for selecting said predetermined magnitude, from among a plurality of selectable magnitudes, of stored energy, for converting said abnormal cardiac rhythm." This is a means-plus-function element. The disclosed structure is the control register 48 and the associated circuitry shown in Figure 1.

Claim 3 of the '750 patent includes: "said control signal is a serial binary control word; and further comprising a control register for converting said serial binary control word into a parallel binary control word; and a digital-to-analog converter for converting said parallel binary control word into a corresponding analog signal, said analog signal being said signal representative of said control signal." These claim elements correspond directly to structures in the physician-operated embodiment in Figures 1 and 2, which is externally programmable. The control register is the same element 48 in the same Figure 1. In the '750 patent, the receiver 18 transmits the serial binary control word to control register 48, where it is converted to a parallel binary control word for the selected energy level. The parallel binary control word is sent along line 50 to the digital-to-analog converter 108, where the signal is converted to an analog output that is sent to comparator 100.

Although testimony from CPI's Dr. Bourland on this point is extrinsic evidence that is not critical to the court's decision, he testified on cross-examination that the control register 48 and the digital-to-analog converter are "essential components that permit the energy levels for cardioversion to be programmed or changed once the device has been implanted," and that the control register can be "externally loaded with different control information indicative of different energy levels." Tr. 953. The questions were asked in the context of the '472 patent, but the answers apply equally to the '750 patent, which shares the same specification and diagrams. In other words, CPI's expert witness was testifying that the claim elements identified in Claim 3 of the '750 patent were "essential components" of the externally programmable physician-operated embodiment shown in Figures 1 and 2.

Thus, every element of Claim 1 of the '472 patent appears in the same or a narrower form in Claim 3 of the earlier

'750 patent, which had expired before the period of alleged infringement in this case. Claim 1 of the '472 patent is invalid as a matter of law for obviousness-type double patenting.

Claim 18 of the '472 patent claims a method for using the externally programmable cardioversion device of Claim 1. CPI has not identified any basis for reaching a different result on the double patenting issue as between Claim 1 and Claim 18. The method of using the device of Claim 1 is sufficiently obvious from the description of the device itself that the difference between the device claim and the method claim cannot save the method claim from the same double patenting defense. Accordingly, St. Jude is also entitled to judgment as a matter of law holding that Claims 1 and 18 of the '472 patent are invalid for obviousness-type double patenting.[15]

IV. '472 Invalidity-Obviousness

At trial St. Jude asserted that Claims 1 and 18 of the '472 patent are invalid under 35 U.S.C. § 103 as obvious from the prior art. The jury rejected the obviousness defense as to each of the asserted claims. St. Jude has moved for judgment as a matter of law on the defense, or in the alternative for a new trial based on the weight of the evidence. The court denies St. Jude's motion in both respects as to the '472 patent, though the issue should be part of any new trial needed as a result of Dr. Bourland's deliberately false testimony.[16]

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[15] The court denies St. Jude's alternative motion for a new trial on the issue because the issue must be resolved as a matter of law.

[16] The briefing on the obviousness issue for the '472 patent is contained in Docket Nos. 813, 843, and 867.

A. General Principles of Obviousness

Section 103(a) provides in relevant part that a claimed invention may not be patented "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

The ultimate determination on the issue of obviousness is treated as a question of law. The decision is based on factual inquiries that include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal*, 231 F.3d 1339, 1343 (Fed. Cir. 2000).

An issued patent is presumed to be valid. 35 U.S.C. § 282. The party asserting invalidity based on obviousness must prove invalidity by clear and convincing evidence. *E.g.*, *WMS Gaming Inc. v. International Game Technology*, 184 F.3d 1339, 1355 (Fed. Cir. 1999); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1459 (Fed. Cir. 1984) (reversing finding of obviousness). The Federal Circuit has often said that it may be easier to satisfy the burden if the party asserting invalidity can show that the relevant prior art was not presented to or considered by the patent examiner. *E.g.*, *WMS Gaming*, 184 F.3d at 1355, citing *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988). The burden remains the same, nevertheless.

These legal principles, together with the standards that apply to motions for judgment as a matter of law and motions for new trials based on the manifest weight of the evidence,

establish high barriers to St. Jude's motions on the defense of obviousness. To win judgment as a matter of law, St. Jude must show that, when all the evidence is viewed in the light reasonably most favorable to CPI, any reasonable jury would have been required to find that St. Jude had shown by clear and convincing evidence that the claimed invention would have been obvious to one of ordinary skill in the art. *E.g.*, *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1354-55 (Fed. Cir. 2000) (reversing denial of judgment as a matter of law); *see also Electro Scientific Industries, Inc. v. General Scanning Inc.*, 247 F.3d 1341, 1349 (Fed. Cir. 2001) ("This court reviews the district court's conclusions on obviousness, a question of law, without deference, and the jury's underlying findings of fact for substantial evidence."), citing *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1359 (Fed. Cir. 1999) ("[W]e first presume that the jury resolved the underlying factual disputes in favor of the verdict winner and leave those presumed findings undisturbed if they are supported by substantial evidence. Then we examine the legal conclusion *de novo* to see whether it is correct in light of the presumed jury fact findings."). To win a new trial on the obviousness defense, St. Jude must show that the jury's decisions to reject the defense were contrary to the manifest weight of the evidence, giving due regard for the jury's role as the trier of fact.

B. The '472 Patent

The improvement deemed patentable in the '472 patent was the ability to program externally the energy levels used for cardioversion. Other aspects of Claims 1 and 18 of the '472 patent were known in the prior art. The other aspects were shown in the 1970 Schuder article (Ex. 241) and the

1974 Denniston patent, U.S. Patent No. 3,805,795 (Ex. 246). *See* Tr. 1875-77 (Rickards).[17]

At the time of the claimed invention, external defibrillators were designed so that energy levels could be adjusted by the operator. Tr. 270 (Tacker); Tr.1964-65. (Rickards). At the same time, implantable pacemakers were also externally programmable for rate and energy levels. Tr. 1883-84; 1919-20 (Rickards).

St. Jude's obviousness theory is that a person of ordinary skill in the art (a) would have recognized from the external defibrillator technology the value of such external programmability, and (b) would have turned to the existing implantable pacemaker technology to solve the problem. *See* Tr. 1884-85.[18]

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[17] There was a dispute at trial over whether Schuder described the same type of catheter electrodes used in the '472 patent, but Denniston also used catheter electrodes. Tr. 1926-29.

[18] St. Jude's obviousness theory on the '472 patent is based primarily on the testimony of Dr. Anthony Rickards, a cardiologist. At trial, CPI tried an extraordinary and deceptive tactic with Dr. Rickards. In an attempt to impeach Dr. Rickards, he was asked: "Do you recall when you were asked at the deposition, you were asked: Doctor, what's the basis for your opinion of obviousness? And that you responded by saying: I'd like to take a recess, I need to take a break. And that you then conferred with [St. Jude counsel] Mr. Olson to figure out what the basis of your opinion was?" Tr. 1913. If that were a fair description of what had actually happened, of course, that would certainly be fair game for cross-examination. When the deposition transcript was read, however, it turned out that the reality had been different. Dr. Rickards had responded: "Can we have a two-minute time out at this stage? I'm not trying to avoid it. My response is going to take a little bit

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The challenge in any obviousness case is to view the problem as it seemed at the time, more than 25 years ago in this case, without being misled by the 20/20 clarity of hindsight. "In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 664 (Fed. Cir. 2000), citing *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998).

The problem for St. Jude is that there is no explicit prior art reference suggesting this combination of pacemaker programming technology with the new implantable cardioverters, nor is there any evidence that people skilled in the field were talking about the possibility. *See* Tr. 268-71 (Tacker).

The lack of explicit suggestion is not necessarily insurmountable, at least as a matter of law. The suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *SIBIA Neurosciences*, 225 F.3d at 1356; *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997) ("sugges-

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of time. Or do you want that a little in summary fashion?" CPI's lawyer responded: "Why don't you give the high points quickly." In other words, Dr. Rickards indicated he was ready at that point to summarize his opinion. Then, however, before Dr. Rickards could do so, the lawyer for CPI changed his mind and said "Let's take a break." *See* Tr. 1914. At trial, therefore, CPI's lawyers tried to impeach Dr. Rickards by using the break that *they had requested* while their own question was pending.

tion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art").

Nevertheless, it is difficult to show that a reasonable jury could not reach any conclusion other than to find by clear and convincing evidence that a person of ordinary skill in the art would have derived from the prior art the suggestion that was never made explicitly. That is a much greater challenge than the defendant faced in *SIBIA Neurosciences*, where the obviousness defense was based on a suggestion explicit in the prior art. 225 F.3d at 1357.

The court heard and saw the same evidence the jury did. St. Jude put on evidence of a strong obviousness defense on the '472 patent. The suggestion that it would have been natural to look to pacemaker technology to provide the technology to program energy levels has considerable force. Both types of devices are implantable and are designed to manage cardiac rhythms. CPI's Dr. Tacker agreed that pacemaker technology would be one reasonable place to look to solve technical problems for implantable defibrillators. Tr. 359. Two of the '472 inventors indicated in 1978, a few years after the invention, that programmability in other inventors' implantable defibrillators was obvious from pacemaker technology. Tr. 393-95 and Ex. 1748. In fact, CPI itself prevailed in a pacemaker patent case by arguing that a combination of prior art from implantable and external devices showed that a claimed invention was obvious. *See Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1573-74, 1577-79 (Fed. Cir. 1983) ("Faced with a rate-limiting problem, one of ordinary skill in the art would look to the solutions of others faced with rate-limiting problems."). (In the *Medtronic* case, however, the trier of fact had found in favor of the invalidity defense, so the case offers limited support for a motion seeking to overturn a verdict.)

Despite its force, St. Jude's argument is still vulnerable to the charge that it is based on hindsight. For example, at the time of the '472 application, the established pacemaker companies were not showing much interest at all in Dr. Mirowski's new implantable defibrillators. *See* Tr. 1921, 1930-32. In addition, of course, relying on an implicit suggestion from the prior art is more difficult for a defendant. For purposes of these motions, the court must also credit Dr. Tacker's testimony that those working in the field in 1974 were focused on trying to increase the available energy for cardioversion. They simply were not worrying at that time about features that would allow them to reduce energy to less than the maximum available energy. Tr. 374-76.

In light of the high standard of proof—clear and convincing evidence—and the stringent standards that apply to these post-verdict motions, the court is not persuaded that St. Jude is entitled to relief on the obviousness defense to the '472 patent, either as a matter of law or in the form of a new trial based solely on the weight of the evidence. As discussed elsewhere in this entry, however, the court finds that St. Jude is entitled to a new trial on this issue and others as a result of the deception by Dr. Bourland.[19]

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[19] Regarding the '472 patent, the court has not needed to reach the asserted evidence of the "secondary" or "objective" indicia of non-obviousness. That evidence is problematic at best because it deals with products that involve numerous features and patents, and because the license agreements were sweeping cross-licenses between competitors for entire portfolios of patents. As a result, there is only the most tenuous nexus between the objective indicia and the claimed invention. *See, e.g., SIBIA Neurosciences*, 225 F.3d at 1358-59 (directing judgment as a matter of law finding patent invalid for obviousness where patentee failed to establish

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V. '472 Infringement

On the '472 patent, the case was submitted to the jury on CPI's assertions that St. Jude's devices infringed Claim 1 and Claim 18. The jury found that both claims were infringed. St. Jude has moved for judgment as a matter of law or in the alternative for a new trial on the findings of infringement.[20]

The jury's findings of infringement are findings of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). St. Jude is entitled to judgment as a matter of law only if no reasonable jury could have found in CPI's favor on an issue, even when all the evidence is viewed in the light reasonably most favorable to CPI when CPI is given the benefit of conflicts in the evidence and any reasonable inferences from the evidence. *E.g.*, *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305, 1309 (Fed. Cir. 2001) (affirming grant of judgment as a matter of law on non-infringement); *Odetics, Inc. v. Storage Technology Corp.*, 185 F.3d 1259, 1269 (Fed. Cir. 1999) (reversing judgment as a matter of law on non-infringement). To obtain a new trial on the findings of infringement, St. Jude must show that the jury's verdict was contrary to the manifest or overwhelming weight of the evidence on that issue.

A. Claim 18

Claim 18 claims a method for using a cardioverting device. The decisive issue concerning Claim 18 depends on the basic difference between using a device that automatically senses and then treats an abnormal cardiac rhythm and using

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[Footnote continued from previous page]

nexus between licensing activity and merits of the claimed invention).

20 This motion is briefed in Docket Nos. 815, 845, and 863.

a device that requires manual diagnosis and manual intervention to trigger the delivery of therapy.

One essential element of the method claimed by Claim 18 is the step of "sensing an abnormal cardiac rhythm, wherein cardioversion is required." The court previously construed this element as a step-plus-function element subject to 35 U.S.C. § 112 ¶ 6 because the element is stated at so abstract a level. Entry on Claim Construction at 43, 2000 WL 1765358, at *23-24. The '472 patent does not disclose any automatic method of sensing an abnormal cardiac rhythm. Either the patient or the doctor must detect the abnormal rhythm and must then decide to initiate treatment. Both techniques involve the exercise of human judgment on the spot.

The court interpreted the element of "sensing an abnormal cardiac rhythm" as "limited to the disclosed sensing methods of (1) displaying an ECG signal for observation and interpretation by a physician, or (2) direct observation of the heartbeat by the physician or patient, or (3) sensing methods equivalent to method (1) or (2)." Entry on Claim Construction at 44; *see also* Final Inst. No. 31 (also instructing that the doctrine of equivalents applied to the claim element).[21]

In normal operation, the evidence is undisputed, all of the accused St. Jude devices use sophisticated electronics and

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[21] Apart from the fact that the "sensing" step is a step-plus-function limitation, another reason to restrict the claim to manual sensing procedures is that the '472 patent's written disclosure does not support a claim to automatic sensing. If the court had construed the claim to reach automatic sensing, the claim would likely be invalid under the written description and enablement requirements of 35 U.S.C. § 112 ¶ 1. See the discussion above in Part II concerning the written description requirement as applied to the '472 patent's claim to cover ventricular devices.

software to operate automatically to detect abnormal cardiac rhythms and to treat them without any intervention by a human being. *See* Tr. 2829-31 (St. Jude's Malkin). In ordinary and automatic operation in a patient, the St. Jude devices do not use the step of "sensing an abnormal cardiac rhythm" as defined by Claim 18 of the '472 patent.

CPI does not attempt to argue that an automatic device is equivalent to a manual device. In an effort to show infringement of this claim element, however, Dr. Bourland testified for CPI that the St. Jude programmers could be used in such a way as to infringe this claim element. A programmer is the external console that a physician can use to communicate with the implanted device. The programmer is used in the physician's office or laboratory to test, monitor, and program the implanted device.

The St. Jude programmers can display the patient's ECG signal. The programmers also have a feature known as the "programmer controlled shock" or "PCS" button. Dr. Bourland seemed to equate the mere display of the ECG signal with "sensing an abnormal cardiac rhythm." *See* Tr. 925-26. He omitted from his analysis the exercise of human judgment in response to the signal, to "sense" whether the rhythm is normal or abnormal, and whether or not cardioversion is required.

CPI argues that the St. Jude devices can be operated manually by a physician using a programmer to operate the implanted device. Viewing the evidence in the light reasonably most favorable to CPI, it is at least theoretically possible for a physician: (1) to view an ECG signal on the programmer, (2) to decide that a patient's current rhythm is abnormal and requires cardioversion, and then (3) to use the PCS fea-

ture to deliver a therapeutic shock. *See* Hardage Dep. at 104-05 (Ex. 5118E).[22]

The problem for CPI is that it presented no evidence at all that any physician has ever used a St. Jude device in this manner. The only evidence on the subject is that Dr. Dorian does not use the PCS feature to administer therapeutic or "rescue" shocks during testing. He does not do so because of the 15 to 20 second delay required, as compared to the one or two seconds needed to use the external defibrillator that must always be available during testing. Tr. 225860. As Dr. Dorian explained, "15 to 20 seconds of ventricular fibrillation seems like a lifetime and you definitely don't want to take that long if you can possibly avoid it." Tr. 2259.

To hold St. Jude liable for infringement on this method claim—whether for inducing infringement or contributory infringement or direct infringement—CPI was required to come forward with some evidence of actual use of the infringing method by someone. *See Met-Coil Systems Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) (absent direct infringement of the patent claims, there can be neither contributory infringement nor inducement of infringement). A method claim is not infringed by the sale of a device that is merely capable of being used in an infringing manner. Actual infringing use must be shown. *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 773-75 (Fed. Cir. 1993) (reversing finding of infringement of method claims where no actual infringing use was shown); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1374

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[22] The Hardage deposition is one of several depositions from which portions were introduced into evidence at trial. The cited trial exhibit is a transcript of the deposition showing which portions were read to the jury.

(Fed. Cir. 1991) (method claims held not directly infringed by the mere sale of an apparatus capable of performing the claimed process).

Even under the deferential standard that applies on a motion for judgment as a matter of law, in the absence of evidence of actual infringing use, there simply is no basis for a finding of infringement of Claim 18. CPI's suggestion that the jury was "free to conclude" that such use had occurred is a baseless invitation for speculation. St. Jude is entitled to judgment as a matter of law on the claim for infringement of Claim 18 of the '472 patent. In the alternative, St. Jude is entitled to a new trial on the issue because of the manifest weight of the evidence showing no actual infringing use of the claimed method.[23]

B. Claim 1

The principal infringement issues concerning Claim 1 arise from the fact that the St. Jude devices are designed to deliver cardioverting electrical shocks with a particular type of waveform that appears when the electrical operation of the device is displayed on a graph. The waveform is biphasic

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[23] CPI asserted in its brief that Hardage's testimony "establishes that physicians have in fact used the PC shock button to deliver therapy to patients." Docket No. 845 at 15, citing Hardage Dep. 104, lines 6-16. In fact, Hardage testified at page 104 only that he had witnessed physicians use the PCS feature, but not that they had done so to administer a therapeutic cardioverting shock. Hardage then explained at pages 105 and 106 that he had seen physicians use the PCS feature to test the device and the connections with the leads, but that he could not recall ever seeing a physician program energy levels for an emergency rescue of a patient in distress in an arrhythmia. The jury could not reasonably find infringing use based on Hardage's testimony.

and truncated. To make sense of that description, it is necessary to compare it to a monophasic and non-truncated waveform.

A wave is monophasic when the electrical discharge all occurs in one direction through the electrical circuit. When the voltage is displayed on an ECG, the signal is deflected in only one direction from the zero voltage baseline. A wave is biphasic if the electrical discharge occurs in a current that goes first in one direction through the circuit and then in the opposite direction. The display of such a wave shows a voltage deflection first in one direction from the zero-voltage baseline and then, a millisecond or so later, in the opposite direction. *See* Tr. 854 (Bourland).

If the discharge from the capacitors in an ICD occurs without being stopped or "truncated" by a switch, the energy discharged starts out as a large surge that decays exponentially toward zero over a period measured in milliseconds. However, if a switch interrupts or truncates the discharge after a few milliseconds, the energy will start out at a high level, decay a small amount, and then drop back to the zero-voltage baseline without the (relatively slow) exponential decay toward zero. The diagrams below show on the left a monophasic non-truncated waveform and on the right a biphasic truncated waveform:

[Diagrams]

The evidence shows without dispute that, for purposes of cardioversion, biphasic and truncated waveforms are safer and more effective than monophasic and non-truncated waveforms. *See*, *e.g.*, Tr. 946-47 (CPI's Bourland) (truncated waveform is more effective at lower energy levels); *see also* Tr. 2823 (St. Jude's Malkin) (truncated waveforms are safer and more therapeutic). The evidence also shows that the truncated waveform was known to those skilled in the art even before the '472 patent application was filed. Tr. 656-57 (Mower).

The evidence also shows without dispute that when a truncated waveform is used, a significant fraction of the energy stored in the capacitors is not discharged. The switch that truncates the discharge has the effect of leaving about one-third or 30 percent of the energy still in the capacitors. Tr. 941, 944-45 (Bourland).

1. Switch Means

The first contested element of Claim 1 is the "switch means for controlling the discharge of the stored energy into the heart of the wearer." The element is in means-plus-function form. The disclosed structure that corresponds to the stated function is a discharge switch, labeled as element 84 in Figure 1. *See also* Final Inst. No. 25. This switch responds to a signal indicating that all necessary conditions for discharging the stored energy have been met. Upon receiving such a signal, the switch changes its state and the energy stored on the capacitor is fired through the switch to an electrode and into the heart of the wearer.

CPI presented evidence demonstrating that the accused devices also contain a structure that releases energy stored in the capacitor into the heart. CPI's engineering expert, Dr. Bourland, testified that the "H-bridge" structures in the accused St. Jude products perform the function recited in the claim and that they are structures equivalent to the discharge switch disclosed in the patent. Tr. 853-55. Dr. Bourland is a person skilled in the relevant art, and he was such at the time of the '472 invention and application.

The evidence is undisputed that the "H-bridge" structures found in St. Jude's accused products actually contain multiple switches. These multiple switches operate together to generate discharge energy in a truncated biphasic waveform.

St. Jude contends that the use of the H-bridge structure to create a release of cardioverting energy in a truncated bi-

phasic waveform does not infringe the "switch means" limitation as a matter of law. However, the claim language itself does not specifically call for any particular waveform. Further, the specification does not describe the structure or function of the disclosed discharge switch in terms such as monophasic or biphasic, truncated or non-truncated.

CPI also points out that the accused products can be programmed so that their Hbridge switches release the stored energy in a monophasic waveform. Tr. 2362 (St. Jude's Fayram); Tr. 2847-48 (St. Jude's Malkin). CPI argued to the jury that it could find infringement of this element of the device claim based only on the fact that St. Jude's devices merely *can be programmed* to deliver a monophasic and nontruncated waveform. Tr. 3359. That is correct as a matter of law. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 622-23 (Fed. Cir. 1995) ("an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes"), citing *Paper Converting Mach. Co. v. MagnaGraphics Corp.*, 745 F.2d 11, 20 (Fed. Cir. 1984) ("imperfect practice of an invention does not avoid infringement"), and *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984) (35 U.S.C. § 271(a) "prohibits, on its face, any and all uses of a patented invention").

The evidence, when viewed in the light reasonably most favorable to CPI, shows that both biphasic and truncated waveforms were known to those of ordinary skill in the art when the '472 patent issued. The fact that switches that generate such waveforms are not described in the '472 patent does not prevent the jury from having treated them as equivalent to the generic switch means disclosed in the '472 patent. The jury could reasonably find that the switch means element is present in the accused St. Jude devices.

2. Selecting Means

The "selecting means" element of Claim 1 requires "selecting means responsive to said programming commands received by said receiving means for selecting said predetermined magnitude, from among a plurality of selectable magnitudes, of stored energy, for converting said abnormal cardiac rhythm." This element is a means-plus-function element. The selecting means structure is control register 48 and the associated circuitry.

The programming commands referenced in the selecting means element are "the signals transmitted to the device from external to the skin of the wearer that designate a particular magnitude of energy." Final Inst. No. 27. The court interpreted the selecting means element of Claim 1 to mean that the "designated magnitude of energy will be stored on the capacitor and then discharged into the heart of the wearer." Most important for these purposes, the court instructed the jury: "Claim 1 recites a device in which the amount of stored energy is essentially the same as the amount of energy designated to cardiovert the heart." Final Inst. No. 27.

CPI's expert Dr. Bourland testified that the truncated waveforms used in the St. Jude devices leave about one-third of the stored energy in the capacitors. Tr. 941, 944-45. No evidence disputes that point. By no stretch of the imagination or English language is two-thirds of the energy "essentially the same" as the full amount of the energy stored. Consider, for example, a client who tells a lawyer "I'll pay you 'essentially the same amount' you billed me," and who then sends a check for two-thirds of the amount billed, or a defendant who tells a judge that he will pay "essentially the same amount" as the court's judgment ordered him to pay, and who then pays only two-thirds the specified sum.

CPI argues that the court erred by instructing the jury that the amount of the stored energy must be "essentially the same as the amount of energy designated to cardiovert the

heart." That issue had not been part of the original claim construction process, but it arose during trial. The Federal Circuit's decision in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, (1996), does not forbid the court from addressing significant claim construction issues that may arise during trial, despite everyone's best efforts to present important issues much earlier. (In this case, the claim construction briefs asked the court to interpret no fewer than 25 phrases in three patents.) The court also does not recall that CPI objected to that aspect of the instruction on the "selecting means." *See* Tr. 2724.

In any event, the court stands by the jury instruction. The language of the claim equates the amount of the stored energy with the energy actually used for cardioversion:

> selecting means responsive to said programming commands [which designate a predetermined magnitude of stored energy for converting the abnormal cardiac rhythm] received by said receiving means for selecting said predetermined magnitude, from among a plurality of selectable magnitudes, of stored energy, for converting said abnormal cardiac rhythm.

'472 Patent, col. 9, *ll.* 2126 (emphasis added). In other words, the programming commands specify the amount of energy to store, and the same magnitude of energy is used for converting the heart. There is no indication in the claim or the specification that the amount of energy delivered to the heart would ever be appreciably less than the entire amount stored in the capacitors pursuant to the programming commands. To have the amounts be essentially the same, the de-

vice must deliver a non-truncated waveform that decays exponentially to zero.[24]

In post-judgment briefing, both sides agree that no evidence supports a finding that the accused St. Jude products are capable of being programmed to deliver charges with a non-truncated waveform. CPI disagrees with the court's claim construction, but agrees that if the court has correctly interpreted the "selecting means" element of Claim 1, St. Jude is entitled to judgment as a matter of law on the issue. St. Jude's motion for judgment as a matter of law is granted, and the accused products did not infringe Claim 1 of the '472 patent.

3. Initiating Means

St. Jude also contends its devices lack the Claim 1 element of "initiating means for initiating the discharge of converting energy into the heart of the wearer after the stored energy has reached said predetermined magnitude." This element is a means-plus-function element governed by 35 U.S.C. § 112 ¶ 6. The court has construed the element to mean that an accused device contains "initiating means" if it contains structures identical or equivalent to (1) AND gate 82 as shown in Figure 3 and described in the specification, or (2) the manually operated discharge button 40 as shown in Figure 2 and described in the specification. The AND gate initi-

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[24] The court's decision is based on the requirement that the stored energy and the delivered energy be essentially the same. The court's decision is not based on any requirement that the programmed energy level be the same as the delivered energy. St. Jude's Malkin testified that the St. Jude devices will estimate for the physician the delivered energy that will result from the programmed commands when a truncated waveform is used. Tr. 2859-60.

ates a cardioverting shock when two conditions are satisfied: (a) the capacitors have charged to the correct level, and (b) the arrhythmia is still present.

Dr. Bourland testified that the St. Jude devices use software (or "firmware") as their initiating means equivalent to the AND gate. Tr. 873-74; *see also* Tr. 2081-82 (St. Jude's Clem) (firmware requires confirmation that charging has been completed and that arrhythmia is still present). Dr. Bourland also testified that the PCS button on the St. Jude programmers serves as the initiating means equivalent to the manually operated discharge button 40 from Figure 2 of the '472 patent. Tr. 876-78.

St. Jude argues that Dr. Bourland was wrong on these matters, but St. Jude has not shown that no reasonable jury could have credited his testimony on the initiating means element.

Because the accused St. Jude devices do not contain the "selecting means" element of Claim 1, the court grants St. Jude's motion for judgment as a matter of law on CPI's claim that St. Jude infringed Claim 1 of the '472 patent. However, apart from the new trial granted because of Dr. Bourland's deception, the court denies the alternative motion for a new trial on the infringement issue because the issue depends solely on a question of law, the interpretation of the "selecting means" element.

VI. '288 Invalidity—Best Mode Violation

The court now turns to issues affecting the '288 patent for multimode operation of ICDs. The jury found that the '288 patent was not infringed. The jury also rejected St. Jude's defenses asserting that the '288 patent was invalid and unenforceable. The first issue is whether the '288 patent is invalid because the inventors violated the "best mode" requirement of 35 U.S.C. § 112 ¶ 1 by failing to disclose in the

patent the custom-designed battery that was made for them at considerable expense.

As part of the exchange an inventor makes in return for exclusive rights to practice an invention, the inventor must "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112 ¶ 1. "The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001).

The inventors on the '288 patent worked with Honeywell in the 1970s to develop a special battery for an ICD. When the inventors applied for the '288 patent in December 1980, they considered the Honeywell battery to be the best available battery for the invented device. They failed to disclose that battery in the patent specification.

The jury heard the evidence of this defense and rejected it. After reviewing the evidence presented at trial, however, it is clear that St. Jude established all elements of the best mode defense as a matter of law. CPI's attempts to rebut the defense are based on erroneous interpretations of the law and must be rejected. St. Jude is entitled to judgment as a matter of law holding the '288 patent invalid for failure to comply with the best mode requirement of § 112 ¶ 1.[25]

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[25] The best mode issue is briefed in Docket Nos. 816, 855, and 869.

A. Elements of a Best Mode Invalidity Defense

A patent is presumed valid, and a party challenging its validity must prove invalidity by clear and convincing evidence. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1064 (Fed. Cir. 1998) (affirming JMOL for best mode violation). To prove its best mode defense, St. Jude was required to satisfy a two prong test. The Federal Circuit recently described the test:

> Our case law explicating the best mode requirement focuses on a two-prong inquiry. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1548, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212, 37 USPQ2d 1388, 1390 (Fed. Cir. 1996). Second, if the inventor possessed a best mode, the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. *Fonar*, 107 F.3d at 1548, 41 USPQ2d at 1804; *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *U.S. Gypsum*, 74 F.3d at 1212,

37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036-37.

Eli Lilly, 251 F.3d at 963.

The second prong does not require proof that the inventor intended to conceal the best mode or otherwise acted with improper intent. An objective failure to make sufficient disclosure is sufficient. *See Dana Corp. v. IPC Ltd. P'ship*, 860 F.2d 415, 418 (Fed. Cir. 1988) (accidental or intentional concealment can support best mode defense); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed. Cir. 1987) (same). Whether inventors complied with the best mode requirement is a question of fact. *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531 (Fed. Cir. 1991).

The '288 patent does not make any claims regarding a battery, but it asserts that the invention is "an implantable heart stimulator" and "a method of heart stimulation using an implantable heart stimulator." Thus, the plain language of the claims states that the invention is a fully functional heart stimulator. The power source therefore is subject matter necessary to the operation of and directly related to the claimed invention. *See Dana Corp.*, 860 F.2d at 419-20 (holding that patent document failed to disclose unclaimed subject matter that the inventor considered necessary for carrying out the best mode of the invention).

A battery is obviously essential to an ICD implanted in the human body. This is not a case where the claimed invention relates only to a part or one aspect of a larger device. *See, e.g., Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281, 1288, 1297 (Fed. Cir. 2000) (holding that asserted best mode did not relate directly to the claimed invention; distinguishing *Dana Corp.*). If Dr. Mirowski and his co-inventors knew, when they filed the '288 application in December 1980, of a best battery for practicing the invention claimed in the '288 patent, they were required to disclose it.

B. The Evidence on the Honeywell Battery

Batteries for ICDs must supply much more power than pacemaker batteries, and in light of their purpose they must be highly reliable. Tr. 679-80, 682 (Mower); Langer Dep. at 87 (Ex. 5057). The evidence showed that the '288 inventors had paid Honeywell several hundred thousand dollars over several years in the late 1970s to custom-design a new lithium and vanadium pentoxide battery for use in ICDs. Tr. 683 (Mower); Heilman Dep. at 33-34, 106 (Ex. 5069). The '288 patent application disclosed no information about a battery, battery chemistry, or other power source.

Dr. Mirowski and his team did the first human implants of early ICDs in February 1980. By that time, the new Honeywell lithium battery had been tested and the inventors were confident it would work. Tr. 687 (Mower). Other researchers were working on ICDs at that time, but no one else was doing human implants of ICDs at that time.

On the witness stand, Dr. Mower tried hard to avoid testifying that the Honeywell battery was the best ICD battery that he and the other inventors knew about at the time of the '288 application. *See*, *e.g.*, Tr. 687-88. But Dr. Mower eventually conceded that they did not know of any other that would work as well. Tr. 688. The team had not tested any other. *Id.*

Dr. Stephen Heilman was also an inventor on the '288 patent, and he testified by deposition. *See* Tr. 2088; Ex. 5069 (Heilman Dep. transcript). He also tried to resist the concessions. He testified that other batteries with other technologies were available, and some were actually used in test ICD implants in dogs. Heilman Dep. at 108-09. But like Dr. Mower, he also eventually conceded that the Honeywell battery was the best one the inventors knew about. Dr. Heilman testified: "I'm certain there were batteries that could have been used that would have been less reliable but could have been used for an implantable defibrillator. We elected to pay

for the development of *what we considered to be a more reliable battery for this product*." *Id.* at 108 (emphasis added).

Dr. Heilman tried to claim that other suitable batteries were available. But in perhaps the most pointed exchange, Dr. Heilman was asked whether he would have been willing to use in an ICD implant in a member of his family the same battery that he was willing to use in the ICD experiments on dogs. Dr. Heilman testified as follows:

> Q But you wouldn't have used one of those [dog implant] batteries in a defibrillator to implant in one of your relatives?
>
> A Well, you—you could. We elected to pay for a high degree of reliability, yeah.
>
> Q But my specific question is: Would you have used one of the commercially available batteries in 1980 and 1981 in a defibrillator that would be implanted in one of your relatives?
>
> A Well, if it was life and death and there wasn't an alternative, yes.
>
> Q Well, as compared to the one that Honeywell developed for you?
>
> A That's why we elected to get a more reliable battery.

Heilman Dep. at 109 (emphasis added).

The evidence from the inventors themselves showed that they had invested hundreds of thousands of dollars and years of work to develop an improved battery for their ICDs. In addition, their contract with the company that developed the battery also barred Honeywell from selling the battery to anyone else without their permission. Heilman Dep. at 38.

The testimony from the inventors showed beyond any reasonable dispute: (a) that the claimed invention could not be practiced without a battery; (b) that at the time the '288 application was filed, the inventors believed the battery that Honeywell had developed for them was the best available battery for such devices and knew it was the only one that had been tested; and (c) that the '288 patent application did not disclose any battery, battery chemistry, or other information about a power source. The inventors' custom-designed battery was not merely a production detail, commercial detail, or other routine detail that would have been reasonably apparent to those skilled in the art of ICDs. On these points, "reasonable minds could not have differed." *Dana Corp. v. IPC Ltd. P'ship*, 860 F.2d 415, 420 (Fed. Cir. 1988) (reversing denial of judgment as a matter of law on best mode defense).

C. CPI's Rebuttals to the Best Mode Defense

CPI offers two responses to this evidence. Neither response involves any dispute as to what the facts were. As a matter of law, neither response is sufficient to defeat the best mode defense.

First, CPI contends the Honeywell battery was not the inventors' best mode for the '288 invention because they hoped and expected to have a better battery by the time the '288 device would actually be built and implanted in humans. Dr. Mower testified that the inventors did not intend to use the Honeywell battery in the multimode ICD described by the '288 patent and that the Honeywell battery was never actually used in a multimode ICD. Tr. 534-35, 539, 739. CPI is entitled to the full benefit of that testimony and all reasonable inferences that could be drawn from it. But Dr. Mower also testified that in 1980, the '288 inventors viewed the Honeywell battery as "the best battery that [he] thought could be used inside a human for the first implant in the world,"

and that the better model for multimode ICDs had not even been designed at that time, let alone built. Tr. 680.

The inventors' hope for a better battery in the future does not defeat the best mode defense. The relevant time for the inquiry is the time when the patent application was filed. *E.g.*, *Chemcast Corp. v. Arco Indus. Co.*, 913 F.2d at 923, 927-28 (Fed. Cir. 1990); *Dana Corp.*, 860 F.2d at 418. Just as later discovery of a best mode cannot invalidate a patent, *e.g.*, *Engel Industries*, 946 F.2d at 1533, an inventor's hope for later improvements cannot excuse the failure to disclose the best mode known at the time of application. Given the pace of technological improvements in many fields, almost any inventor could harbor similar hopes. Such hopes do not excuse a failure to comply with the best mode requirement imposed by § 112 ¶ 1.

CPI's second response is that the Honeywell battery was disclosed by Honeywell itself about six months before the '288 application was filed. The inventors gave Honeywell permission to publish information about the specialized battery about six months before the '288 application was filed. *See* Ex. 1762. A short article was presented at the Power Sources Conference in June 1980. Ex. 3044.

Citing *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1346-47 (Fed. Cir. 2000), CPI argues that the inventors were not required to include the battery information in the '288 specification because the information was otherwise available. In *Ajinomoto*, the Federal Circuit affirmed a district court decision rejecting a best mode defense. The key information (in that case the need for a particular gene) was not disclosed in the patent specification. However, the information had been published four months earlier in a Russian publication on genetics, and expert testimony supported findings that one of ordinary skill in the art would have known of the need for the particular gene in any event. 228 F.3d at 1346. In light of that evidence, which the finder of

fact had credited, there was no need to include in the patent specification what would have been known to one of ordinary skill in the art. *Id.* at 1347.

Ajinomoto does not help CPI here because there was no comparable evidence here. No witness testified that one of ordinary skill in the art of implantable cardioverters or defibrillators would have known of the Honeywell battery. When Honeywell published its description, it did not mention defibrillators. It referred only generally to "demanding applications" in "medical and special areas." Ex. 3044 at 8. The description did not mention the ICD inventors, and it was published in a forum for battery specialists, not for cardiologists and inventors of ICDs. There is no evidence that would allow a reasonable jury to find that those skilled in the relevant art would have known of that publication or of the new Honeywell battery.

The best mode requires disclosure so that a person of ordinary skill in the art can practice the best mode of the invention "without undue experimentation." *Nobelpharma AB*, 141 F.3d at 1064. Publication of information without any reference to the invention in question, and in only one forum that those skilled in the relevant art are unlikely to know about, does not fulfill the best mode requirement. Others trying to practice the invention would have been left to repeat the '288 inventors' development work. *See* Heilman Dep. at 41 (person of ordinary skill in the art who wanted to buy or build a battery "would do what we did. He would go to people that supply batteries.").[26]

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[26] The inventors' agreement to allow Honeywell to publish the battery information would be more significant if a best mode violation required proof of intent to conceal. The fact that the inventors also identified a specific microprocessor in the '288 patent (col-

[Footnote continued on next page]

Accordingly, the '288 patent is invalid as a matter of law for failure to disclose the best mode of practicing the invention, which required at the time the application was filed the use of the unique Honeywell battery. The court also grants St. Jude's alternative request for a conditional new trial on the issue based on the overwhelming weight of evidence on the defense.

VII. '288 Invalidity—Obviousness

St. Jude also contends the multimode programming claimed by the '288 patent is invalid as obvious. In the discussion of St. Jude's obviousness defense to the '472 patent above in Part IV-A, the court has set forth the general principles of obviousness. They need not be repeated here. St. Jude's obviousness defense to the '288 patent is much stronger than its obviousness defense to the '472 patent. The court grants judgment as a matter of law and in the alterna-

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[Footnote continued from previous page]

umn 15, *ll.* 32-34) would also be more significant in that event. As noted above, the best mode defense does not require such proof of intent to conceal. *See Dana Corp.*, 860 F.2d at 418 (accidental or intentional concealment can support best mode defense); *Spectra-Physics*, 827 F.2d at 1535 (same). Despite this clear law, CPI argued the issue to the jury in closing in terms plainly implying that the best mode defense required proof of intentional concealment or deception. *See* Tr. 3371 ("they say the inventors duped the Patent Office and the public, willfully withheld the lithium battery technology"); Tr. 3477 ("They say they deliberately withheld the best mode of the battery, deliberately.").

tive a new trial on the obviousness defense to the '288 patent.[27]

This issue revolves around the meaning of "multimode operation." The court interpreted the '288 term "multi-mode operation to treat a detected arrhythmia" to mean: "two or more different modes of therapy capable of being used in sequence to treat a single arrhythmia." Entry on Claim Construction at 49, 53, 2000 WL 1765358, at *27-29. Claim 4 of the '288 patent requires multimode operations "wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion." In Final Instruction No. 35, the court instructed the jury: "For purposes of Claim 4, the term 'cardioversion' applies to the application of non-pacing electrical pulses designed to stimulate sufficient heart tissue to correct an arrhythmia, with energy levels generally below those used for defibrillation." Claim 13 also requires that at least one mode of operation include cardioversion, which was similarly defined for the jury.

St. Jude relies on prior art patents that disclosed the use of different anti-tachycardia pacing modes in sequence to treat a single arrhythmia, together with explicit suggestions in the prior art to combine pacing followed by cardioversion and/or defibrillation. The court addresses first the prior art teaching the use of different pacing modes in sequence to treat a single arrhythmia, and turns then to prior art regarding the use of pacing modes and defibrillation and/or cardioversion modes in sequence.

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[27] The briefing on the obviousness defense to the '288 patent is contained in Docket Nos. 816, 855, and 869.

A. Multiple Pacing Modes

Several prior art patents taught the use of multiple anti-tachycardia pacing modes in sequence to treat a single arrhythmia. For example, Zacouto '399 (U.S. Patent No. 3,857,399; Ex. 1341) described the use of a coupled single pulse several times to try to stop a tachycardia. If that therapy is not successful, it is followed by fixed rate pacing at increasing frequencies. *See* Tr. 2972-74 (Mirhan). Zacouto '399 thus taught multimode therapy, though without cardioversion required by '288 Claims 4 and 13.

Similarly, Baker '502 (U.S. Patent No. 4,280,502; Ex. 839) described the use of single or multiple anti-tachycardia pacing modes. These may include a single-pulse therapy followed by a two-pulse mode in sequence. Tr. 2974.

Pequignot '844 (U.S. Patent No. 3,939,844; Ex. 4069) described the use of multiple types of pacing therapies in sequence and suggested that they could be programmed automatically. Ex. 4069 at col. 5, *ll.* 52-58. The 1974 Haft article also plainly showed the use of multiple pacing modes in sequence. *See* Tr. 420-21 (Tacker); Ex. 1517.

Duggan '870 (British patent GB 2 026 870; Ex. 781) is a Medtronic patent. Duggan '870 also described several modes of therapy in sequence. For tachycardia, Duggan described pacing shocks delivered to single sites in the atrium and ventricle in sequence, followed by pacing shocks delivered to multiple sites simultaneously. Tr. 2981-89. In light of the requirement in '288 Claims 4 and 13 that one mode be "cardioversion," St. Jude emphasizes the fact that another Medtronic patent described this latter therapy of pacing shocks to multiple locations as "cardioversion" capable of capturing a critical mass of the heart. Ex. 1419 (col. 1, *ll.* 41-68).

To defeat the obviousness defense, CPI contends that Dr. Tacker testified that none of the prior art even showed mul-

timode therapy of any kind, even multiple modes of pacing therapy. Docket No. 855 at 16, citing Tr. 278. That testimony was based on a wishful reading of the court's claim construction. During the claim construction proceedings, CPI asked the court to define multimode operation in a way that would allow CPI to argue that all forms of antitachycardia pacing therapy would be deemed one "mode." CPI's proposed interpretation would have had the court distinguish between "antitachy pacing" and "cardioversion" as different modes. *See* Entry on Claim Construction at 49, 2000 WL 1765358, at *27. The court declined to do so. Instead, the court adopted CPI's proposed reading without the parenthetical examples that were intended to become the basis for CPI's argument to rebut obviousness at trial.[28]

In fact, the '288 patent itself describes different forms of pacing therapy as different "modes" of therapy. Columns 4 and 5 of the '288 patent identify as different "modes" of therapy: long-term operating modes, including ventricular

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[28] CPI's effort to include the seemingly innocuous parenthetical examples at the *Markman* claim construction stage of the case illustrates a problem inherent in having the court construe patent claims early in the case, before the court knows what the parties' positions are and before the court may recognize what traps are being laid for the opposing party. When the court decided not to include the parenthetical examples, the court had no idea how those examples might have been used. CPI did not ask the court during the *Markman* proceedings to construe "multimode operation" so as to say that the only different modes were (a) antitachycardia pacing, (b) cardioversion, and (c) defibrillation. The court would have rejected such an interpretation as contrary to the plain language of the '288 patent itself. CPI instead tried the more subtle approach of slipping the parenthetical examples into the definition.

fixed rate pacing, atrial fixed rate pacing, ventricular demand pacing, bifocal pacing, and automatic defibrillation, as well as short-term operating modes that include cardioversion, automatic patient warning, and automatic ventricular tachycardia control operations, including ventricular override pacing, rapid atrial pacing, ventricular coupled pacing, and automatic cardioversion. Plaintiffs told the examiner the same thing in the reexamination proceeding in 1999. Ex. 4052 at 4052.186 ("sub-mode" as used in specification is synonymous with "mode"); *see also* Tr. 2951-66 (Mihran discussing use of "modes" in '288 patent). Thus, using the term "modes" as it is used in the '288 patent itself, the prior art plainly shows multimode operations involving sequences of different anti-tachycardia pacing modes to treat a single arrhythmia.[29]

B. Pacing, Cardioversion, and Defibrillation

The prior art teaching multiple modes of pacing therapies raise serious questions about the validity of Claims 1 and 10 of the '288 patent, of course. Thus, CPI elected during trial to focus its case on the '288 patent upon Claims 4 and 13, which add the requirement that one of the modes of operation must be "cardioversion."

The Denniston '795 patent (U.S. Patent No. 3,805,795; Ex. 246) taught a device that detects the absence of a heart-

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[29] CPI also asserts the bare conclusion in its brief that eight principal prior art references do not disclose "multi-mode capability." Docket No. 855 at 16. The assertion is plainly wrong, and it is apparently based on CPI's mistaken view of the meaning of multimode capability. The '288 patent itself treats different types of pacing therapy as different "modes" of therapy, so the prior art that teaches different types of pacing therapies in sequence teaches multimode therapy.

beat (an "asystole") and can then respond first with pacing shocks for about 20 seconds, followed by a cardioversion shock. Tr. 2975-77, 2990, 3125-26, 3163-67. The Denniston '611 patent (U.S. Patent No. 3,815,611; Ex. 9004) described a device that operates to provide both pacing and cardioversion shocks. Tr. 2975-76; Ex. 9004, col. 3, *ll.* 10-29.

The Engle '614 patent (U.S. Patent No. 4,403,614; Ex. 95) described a device that combines the ability to deliver pacing shocks and defibrillation shocks, and which emphasizes the value of also being able to deliver cardioversion shocks using energies lower than those required for defibrillation. Engle '614 also taught cardioversion shocks followed if necessary by defibrillation shocks. *See* Ex. 95, col. 1-3. Specifically, Engle '614 stated:

> As the malignant ventricular tachyarrhythmia progresses toward fibrillation, that is, as the R-R interval [between heartbeats] decreases, the energy level of the cardioverting signal may be selectively increased. In a preferred embodiment, as the R-R interval approaches that indicative of the onset of fibrillation, (an R-R interval of 200 msec.) the cardioverting signal energy is increased to a level sufficient for defibrillation. In this latter configuration, the cardioverter of the present invention may be said to be in combination with a body implantable defibrillator. Additionally, a pacemaker, preferably of the demand type, may be incorporated within the inventive combination to maximize the benefits of the implantable device to the patient.

Ex. 95, col. 3, *ll.* 38-52. The '288 patent is almost precisely parallel on this point, explaining the benefits of having the same implantable device perform pacing, cardioversion and defibrillation, '288 Patent, col. 1, *l.* 47 to col. 2 *l.* 37, and

stating that it "would be desirable to have a combined pacer-defibrillator that first could attempt pacing in the presence of such symptoms, and then, if the symptoms persist, attempt defibrillation." '288 Patent, col. 3, *ll.* 2-5.

Similarly, Rizk '628 (U.S. Patent No. 4,114,628; Ex. 831) described a device that delivers pacing shocks but that increases the energy level, depending on the heart's response, up to the point at which it uses a "defibrillating mode." Ex. 831, col. 1, *l.* 38. Although the energy level described by Rizk apparently is below the level actually needed for defibrillation, *see* Tr. 2980-81, the suggestion of using a pacing mode followed by defibrillation mode is clear. It requires no leap at all to think that intermediate energy levels for cardioversion could also be introduced. CPI provided essentially no direct rebuttal to St. Jude's reliance on these items of prior art. Even CPI's Dr. Tacker acknowledged that Engle taught use of the cardioversion mode followed by the defibrillation mode to treat the same arrhythmia. Tr. 412.

St. Jude also relies on the 1974 Haft article to show the compelling motivation to combine pacing modes with stronger modes of therapy. Haft pointed out the medical need for available defibrillation when certain types of pacing was used: "Rapid pacing (over 250/min), coupled, or paired pacing of the ventricle may trigger ventricular fibrillation." Ex. 1517 at 562. In other words, pacing for tachycardia can produce deadly ventricular fibrillation, so a device that performs anti-tachycardia pacing must be able to defibrillate if necessary. It was well known that shocks much stronger (roughly a million times stronger) than those used for pacing may be needed to stop fibrillation. *See* Tr. 3113-16.

St. Jude also relies on Duggan '870, discussed above in Part VII-A, as teaching pacing therapies followed by a form of cardioversion. CPI pointed out at trial that the cardioversion in Duggan '870 was the result not of a single large shock but of a combination of smaller simultaneous pacing

shocks delivered to electrodes attached to multiple sites on the heart muscle. In essence, CPI argues that Denniston taught only pacing and not "true" cardioversion because he used much lower energy levels. *See* Tr. 3134-39 (Mihran cross-examination). That attack by CPI goes to an earlier anticipation defense, however, which St. Jude did not pursue at trial. The attack does not undermine the fact that Duggan taught a form of cardioversion used in sequence after pacing therapy. Even if Duggan did not actually anticipate the "multimode" operation claimed by the '288 patent, it certainly comes "within a hairsbreadth." *See SIBIA Neurosciences*, 225 F.3d at 1359 (directing judgment as a matter of law finding patent invalid as obvious).

C. CPI's Additional Arguments

At page 14 of its brief on the issue (Docket No. 855), CPI has raised several arguments that are scarcely developed, none of which has merit. First, CPI contends that St. Jude failed to address obviousness of the claim as a whole. The only contested element of Claims 4 and 13, however, is the multimode operation claimed by the '288 patent. St. Jude's obviousness defense is aimed directly at that contested element. The court has therefore focused on that element. *See, e.g., Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 717 (Fed. Cir. 1991) (district court properly focused on claim element that was actually disputed).

Second, CPI asserts that St. Jude's obviousness expert, Dr. Mihran, was not a person of ordinary skill in the art *at the time of the invention*. (He was still an undergraduate at the time.) CPI did not challenge Dr. Mihran's qualifications to testify. CPI also has not cited any authority to support the remarkable proposition that only those who were skilled in the art at the time of the invention may be qualified to offer opinions on the issue of obviousness.

Third, CPI asserts without development or citation that "defendants' theories at trial contradicted Dr. Mihran's ex-

pert report." Perhaps CPI was referring to the fact that Dr. Mihran had offered a preliminary opinion in discovery about anticipation, which St. Jude did not pursue at trial, but what matters here is the evidence actually presented at trial.

Fourth and fifth, CPI criticizes Dr. Mihran for being unable to explain how the devices taught by the different prior art patents would be combined into a workable device and for being unable to account for failures of the devices in the prior art. The issue, however, is what the prior art taught those of ordinary skill in the art, not whether the devices described actually worked or were reduced to practice. As St. Jude points out, the embodiments described by the '472 and '288 patents also were not reduced to practice.

Despite CPI's claims to the contrary, neither Dr. Tacker nor any other witness for plaintiff addressed the most critical prior art on the multimode issue—Denniston '795, Denniston '611, and Engle '614—which all taught a combination of at least some form of cardioversion in sequence with other modes of therapy. These prior art references, like Duggan '870, come "within a hairsbreadth of anticipation," and the prior art provides ample motivation and suggestion for the multimode therapy including cardioversion. *See SIBIA Neurosciences*, 225 F.3d at 1359 (reversing district court's denial of judgment as a matter of law after jury rejected obviousness defense).

CPI also contends that the prosecution history of the '288 patent weighs against a finding of obviousness because the "overwhelming majority" of the prior art references were presented to the examiner in either the original issuance or in the reexamination of the '288 patent. That is true, though they were presented as part of a stack of literally hundreds of references, apparently without explanation. While a patentee is not to be criticized for submitting many references upon reexamination (lest it be condemned for having left something out), the probative weight of the reexamination is lim-

ited. In any event, the jury and the court may not simply delegate to the examiner the decision that the law leaves for resolution in the courts.

D. Objective Indicia of Non-Obviousness

CPI relies next upon the evidence of secondary considerations or objective indicia of non-obviousness, such as commercial success, long felt but unresolved need, failure of others to make the invention, unexpected results, licenses of the patent by others, and praise of the invention by the infringer or others. *See, e.g., Ruiz*, 234 F.3d at 660. Although often described as "secondary," the law is clear that such evidence is important and must be considered before a court may find a patent claim invalid for obviousness. *E.g., In re Rouffet*, 149 F.3d at 1355; *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988) (district court erred in finding obviousness based on prior art but without considering objective evidence of non-obviousness); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) (objective evidence must be considered before a conclusion on obviousness is reached, and "is not merely 'icing on the cake'"). Such evidence "may often be the most probative and cogent evidence in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). The proponent of the evidence, however, must establish a nexus between the evidence and the merits of the claimed invention. *E.g., In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Demaco Corp.*, 851 F.2d at 1392.

The evidence of objective indicia here is exceedingly weak. It does not provide substantial evidence sufficient to support the verdict for CPI in the face of the prior art's clear teachings of multimode operation with different pacing modes, with at least one form of therapy called "cardioversion," and with the clear medical motivation for having defibrillation capacity available when anti-tachycardia pacing

therapies are administered because they create a risk of lethal ventricular fibrillation.

There is no evidence of a long felt but unmet need for the multimode therapy feature. Nor is there evidence of the failure of others to make the invention after trying to do so. (The fact that others did not actually invent the claimed invention, which CPI emphasized during trial and in its brief, will always be present in an infringement case, whether the invention was obvious or not.)

Licenses to a patent may be evidence of non-obviousness if they indicate that others in the industry recognize the strength and validity of the patent in question. *See In re GPAC*, 57 F.3d at 1580. Licenses will be entitled to little weight, however, unless the patentee can demonstrate "a nexus between the merits of the invention and the licenses of record." *Id.*, quoting *Stratoflex*, 713 F.2d at 1539 (licenses by others in industry were entitled to little weight when granted as part of settlement of disputes or as part of agreements to license portfolio of several patents plus a trademark).

The license agreements in this case cannot be fairly linked to the '288 patent itself. The license deals were all between competitors involving broad cross-license deals for entire portfolios of ICD patents. The agreements were deals to reach a form of legal peace. They cannot reasonably be deemed evidence that others were acknowledging the strength and novelty of the '288 patent in particular. In other words, there is no substantial evidence of a nexus between the licenses and the '288 invention itself. *See SIBIA Neurosciences*, 225 F.3d at 1358-59 (directing judgment as a matter of law on obviousness; no nexus shown between secondary evidence and merits of claimed invention).

CPI relies heavily upon the commercial success of products including the '288 feature of multimode operations. The trial evidence certainly supports the view that multimode op-

eration has been essential to a commercially successful product at least in the 1990s. *E.g.*, Tr. 281 (Tacker). In light of the extensive evidence from the prior art, however, the commercial desirability of the multimode feature is not enough to support the validity of the claims. *See, e.g., Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997) (affirming judgment as a matter of law finding patent invalid for obviousness; evidence of commercial success did not overcome showing that prior art suggested the claimed invention); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991) (affirming summary judgment finding patent invalid as obvious despite evidence of commercial success even where nexus between merits of invention and commercial success was shown; evidence of obviousness from prior art overcame the secondary evidence as a matter of law); *Merck & Co. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 809 n.* (Fed. Cir. 1989) (reversing district court's finding that patented invention was not obvious; where commercial success was only indicator of non-obviousness, it did not show patent was valid).

One would expect similar evidence of commercial success to be presented whenever one party has patented a desirable but obvious improvement on a successful product, especially if there is no evidence of a "long felt need" or failures of others. As evidence of non-obviousness, this commercial success is not enough to support the jury's verdict in the face of the powerful evidence from the prior art on a host of "multimode" devices. *See Kitch, Graham v. John Deere Co.: New Standards for Patents*, 1966 Sup.Ct. Rev. 293, 332 (1966) ("And if men of skill start to work on the improvement, why does the fact that the patentee was first to perfect the improvement mean the others failed? Perhaps they were only a little slower. This seems a fragile thread on which to hang a conclusion of non-obviousness, particularly in a case where the patentee shows only commercial success but does not show that the commercial potential was perceived or that at-

tempts actually were made that failed."), quoted in 2 *Chisum on Patents* § 5.05[2][a] at 5-581 to 5-582 (2001).

In sum, undisputed evidence shows that the multimode capacity element of Claims 4 and 13 of the '288 patent, which is the only arguably new element of those claims, is rendered obvious by the prior art. The jury's verdict to the contrary is not supported by substantial evidence. Accordingly, St. Jude is entitled to judgment as a matter of law that Claims 4 and 13 of the '288 patent are invalid under 35 U.S.C. § 103(a). In the alternative, the evidence on this issue was so overwhelming that the jury's verdict was contrary to the manifest weight of the evidence. St. Jude would be entitled to a new trial on the issue even if it were not entitled to judgment as a matter of law, and even apart from the effect of Dr. Bourland's deception.

VIII. '288 Enforceability—Inequitable Conduct

St. Jude has moved for judgment as a matter of law or for a new trial on its defense asserting that the '288 patent is unenforceable. St. Jude contends that CPI engaged in inequitable conduct in its efforts to correct its earlier failures to pay the correct maintenance fees for the patent. The court addresses this issue because it might become relevant if a higher court were to disagree with this court's treatment of other issues regarding the '288 patent.[30]

When the '288 patent was issued on October 4, 1983, the patent qualified for discounted fees under 35 U.S.C. § 41(h) because the patent was held by a so-called "small entity." In 1985, the '288 patent was licensed to Eli Lilly & Company, which is anything but a "small entity." From that time forward, full and undiscounted maintenance fees were required

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[30] This issue is briefed in Docket Nos. 816, 855, and 869.

under 35 U.S.C. § 41. In 1987 and 1990, the patentee incorrectly paid maintenance fees at the discounted rate applicable only to small entities. In 1995, the patentee paid the next maintenance fee at the full and correct amount. No effort was made at that time to correct the earlier payments at the discounted small entity rate.

CPI then became involved in a lawsuit with Intermedics in which the '288 patent was at issue. On February 4, 1997, a former CPI patent attorney, Peter Forrest, was deposed in that case. The attorney for Intermedics asked questions about the failure to pay the correct maintenance fees and related documents, thus bringing the problem to the attention of CPI and its lawyers in February 1997.

CPI did not take action to correct the earlier failures to pay the correct fees until March 4, 1998. A CPI attorney then advised the PTO that the earlier inadequate payments had been made at the wrong rates, that the payments had been made in good faith, that the error had been "recently discovered," and that the error had occurred when counsel's files were not properly remarked after the license was issued to Lilly. Ex. 4051A at 266-68. The CPI attorney tendered an additional payment of $2,430 with the March 4, 1998 submission. The PTO accepted the late payment on October 16, 1998 pursuant to 35 U.S.C. § 41(c)(1) and 37 C.F.R. § 1.28(c).

In deciding St. Jude's earlier motion for summary judgment on the defense of intervening rights under 35 U.S.C. § 41(c)(2), the court concluded that the failure to pay the correct maintenance fees caused the '288 patent to lapse from October 4, 1987 to October 16, 1998. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 2001 WL 483973, at *2 (S.D. Ind. May 2, 2001); *accord*, *Haden Schweitzer Corp. v. Arthur B. Myr Industries, Inc.*, 901 F. Supp. 1235, 1238 n. 9 (E.D. Mich.1995); *contra*, *Jewish Hospital of St. Louis v. IDEXX Labs.*, 951 F. Supp. 1, 2 (D. Me.1996). The court

also found, however, that intervening rights could not arise unless the alleged infringer could show that it relied to its detriment upon the lapse resulting from the inadequate fee payments. *See Cardiac Pacemakers*, 2001 WL 483973, at *3, citing *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1554 (Fed. Cir. 1997). At trial, St. Jude did not pursue the reliance issue and the intervening rights theory. Instead, St. Jude argued that CPI engaged in inequitable conduct in its dealings with the PTO to correct the earlier failures to pay the proper fees.

The Federal Circuit has often set forth the elements of the defense of inequitable conduct. For example, in *Semiconductor Energy Lab. Co. v. Samsung Elec. Co.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000), the court wrote:

> Patent applicants are required to prosecute patent applications with candor, good faith, and honesty. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1826 (Fed. Cir. 1995). "[I]nequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Id.* The alleged infringer, whether a defendant in a patent infringement suit or a declaratory judgment plaintiff, must demonstrate by clear and convincing evidence both that the information was material and that the conduct was intended to deceive. *See id.*

At trial, the court instructed the jury on the defense:

> To prove their defense of inequitable conduct, defendants must show, by clear and convincing evidence, that the patent owner or its attorney, with intent to mislead or deceive, withheld or misrepresented information that

> was significant and material to the examiner's evaluation of the application to reinstate the lapsed patent.

Final Inst. No. 50. In response to a specific question on the verdict form, the jury found that St. Jude had not proved the defense of inequitable conduct by clear and convincing evidence.

In its post-verdict motion, St. Jude does not contend that the original failures to pay the proper maintenance fees amounted to inequitable conduct, at least as a matter of law. Instead, St. Jude argues that CPI engaged in inequitable conduct when it applied for reinstatement of the '288 patent in March 1998 without informing the PTO about the litigation involving the '288 patent, CPI's discovery of the fee problem a year earlier during that litigation, and CPI's 1994 application for an extension of the patent at a time when it had lapsed, where CPI certified that all fees had been paid.

St. Jude contends the court should make its own findings on the issue of inequitable conduct. *See generally Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993) (holding that patentee had no right to jury trial on issue of inequitable conduct). In this case, however, the issue was submitted to the jury without objection, and it was not submitted on an advisory basis. Under these circumstances, the court does not make its own independent findings of fact for the first time in considering a post-verdict motion. *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1114 (Fed. Cir. 1996); *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 541 (Fed. Cir. 1990).[31]

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[31] The decision to submit the inequitable conduct defense to the jury offered some tactical benefits for St. Jude. The decision allowed St. Jude to present to the jury evidence that CPI and its pat-

[Footnote continued on next page]

To establish the defense, St. Jude was required to prove by clear and convincing evidence that CPI acted with subjective intent to deceive the PTO when it applied for reinstatement. Confessions of such intent are rare, at least outside Rule 11 colloquies in criminal cases, and St. Jude correctly points out that such intent to deceive must ordinarily be shown by circumstantial evidence. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180-81 (Fed. Cir. 1995) (also noting deference that must be given to fact-finder on issue of intent to deceive). And contrary to CPI's arguments, the court finds that St. Jude's circumstantial evidence—especially the vague reference to the "recently discovered" error more than a year after the issue had first been raised, and without reference to the pending litigation—would have allowed a reasonable jury to find intent to deceive. *See Lipman v. Dickinson*, 174 F.3d 1363, 1370 (Fed. Cir. 1999) ("The fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent.").

On St. Jude's post-trial motion for judgment as a matter of law, however, the issue is whether the evidence of intent to deceive was so powerful that a reasonable jury could not have failed to find intent to deceive by clear and convincing evidence. Perhaps the presentation to the PTO was an honest

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[Footnote continued from previous page]

ent attorneys had submitted false material information to the PTO, and it allowed St. Jude to argue that CPI and its attorneys acted with deceptive intent. If the defense had not been submitted to the jury, all of that evidence would have been heard only by the court. The evidence was not relevant to any other issues the jury had to decide.

effort to come clean with the PTO; perhaps it was not. But as this case was tried, that was a question for the jury, which was properly instructed on the issue and made its decision.

St. Jude relies upon a decision from the Central District of California, *Ulead Systems, Inc. v. Lex Computer & Management Corp.*, 130 F.Supp.2d 1137, 1146 (C.D. Cal.2001), in which the court granted a motion for summary judgment finding that inequitable conduct regarding small-entity fees had been shown as a matter of law, notwithstanding the patentee's assertions of honest mistakes. To support treatment of the issue of intent as a matter of law, the *Ulead Systems* court cited *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1191-92 (Fed. Cir. 1993).[32]

Paragon Podiatry affirmed a grant of summary judgment on the issue of inequitable conduct despite affidavits from those involved denying any deceptive intent. The underlying issue during patent prosecution had been obviousness. The applicant had submitted three affidavits supposedly from disinterested persons to support its position on the advantages of the claimed invention over prior art. 984 F.2d at 1191. It later turned out, and was admitted, that all three affiants held stock in the applicant, that at least one had also been a paid consultant for the applicant, and that none of these facts were disclosed to the examiner. *Id.* The last straw for the court was the fact that all three affiants had "averred with what now conveys the impression of deliberate

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[32] On this point, the district court in *Ulead Systems* also cited *LaBounty Mfg., Inc. v. United States International Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992). In *LaBounty*, however, the Federal Circuit affirmed an administrative law judge's factual findings based on the credibility of the witnesses. The decision offers little support for finding deceptive intent as a matter of law.

artfulness" that they were not employed by the applicant and did not intend to become employed in the future. *Id.*; *see also Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000) (emphasizing the "deliberate artfulness" of the affidavits in *Paragon Podiatry*). In light of that "artful" attempt to give the false impression that the affiants were disinterested, the Federal Circuit affirmed summary judgment despite affidavits from the patentee and its attorney denying any intent to deceive. 984 F.2d at 1191-92.[33]

Several years before *Paragon Podiatry*, the Federal Circuit warned against what it called the "absolute plague" of charges of inequitable conduct in "almost every major patent case." *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (reversing summary judgment where evidence allowed reasonable inference of honest mistake rather than intentional deception). The court added: "A summary judgment that a reputable attorney has been guilty of inequitable conduct, over his denials, ought to be, and can properly be, rare indeed." *Id.* (emphasis in original). The Federal Circuit has also cautioned: "Courts grant JMOL for the party bearing the burden of proof only in extreme cases, when the party . . . has established its case by evidence that the jury would not be at liberty to disbelieve and the only reasonable conclusion is in its favor." *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1375 (Fed. Cir. 2001).

Unless the courts intend to foster the "absolute plague" decried by the Federal Circuit, *Paragon Podiatry* must be

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[33] Also, the finder of fact on the inequitable conduct issue in *Paragon Podiatry* would have been the same district judge who had granted summary judgment based on the paper record. *See* 984 F.2d at 1190.

regarded as one of these "extreme cases," as "rare indeed." The evidence there was extraordinarily powerful. In this case, the evidence of inequitable conduct was debatable. The evidence would have permitted but did not compel a finding of intent to deceive. The evidence also was not so lopsided on the question that a new trial on the issue is warranted. St. Jude's motion for judgment as a matter of law and its alternative motion for a new trial on the defense of inequitable conduct regarding the '288 patent are both denied. However, in the event of a new trial on the '288 patent, based on Dr. Bourland's conduct, discussed next, or for other reasons, the inequitable conduct defense shall be part of the trial.

IX. Dr. Bourland's False Testimony

St. Jude has moved to strike the testimony of Dr. Joe D. Bourland, CPI's chief witness on infringement issues. In the alternative, St. Jude seeks a new trial on issues as to which CPI prevailed at trial and monetary sanctions. The motion is based on proof that Dr. Bourland deliberately gave false material testimony before, during, and after trial. The motion is also based on the roles and knowledge of CPI, its inside counsel, and its principal trial attorneys in this case, the law firm of McAndrews Held & Malloy.

Dr. Bourland's deception seriously undermined the integrity of these proceedings. The court took some actions during trial in an attempt to remedy the problem as it then appeared. It is now clear, however, that those measures were not sufficient to ensure a fair trial for St. Jude. The measures taken during trial were based on the premise that Dr. Bourland's testimony might have been honestly mistaken. Dr. Bourland has now admitted that he deliberately deceived St. Jude, the jury, and the court.

Accordingly, in the event that this court's final judgment in favor of defendants were to be set aside on appeal, St. Jude would be entitled to a further remedy for Dr. Bourland's deception. St. Jude would be entitled to a new trial on all issues

as to which it did not prevail, as well as a financial sanction to compensate St. Jude for the additional expenses of a new trial, including attorney fees, it incurs as a result of Dr. Bourland's deception and CPI's failure to disclose it. St. Jude is also entitled now to a financial sanction to compensate it for the expenses and attorney fees it has already incurred in uncovering and seeking relief from that deception.[34]

A. Dr. Bourland and His Role in the Trial

Dr. Bourland was the single most important witness for plaintiffs. Dr. Bourland is a biomedical engineer. He has a doctorate in physiology and a bachelor's degree in electrical engineering. He has been a faculty member at Purdue University since 1974. Dr. Bourland has been involved in researching and developing cardiac rhythm management devices since he was an undergraduate in the mid-1960s.

Dr. Bourland testified as CPI's principal infringement witness. He testified as to both the '472 and '288 patents. He studied both patents, their claims, and the court's construction of disputed terms in those claims. He also examined St. Jude's accused devices and their accompanying technical manuals. Dr. Bourland opined that all of the accused St. Jude devices infringed both patents. He opined on the issue of equivalents and about the written description issue under the '472 patent. Without Dr. Bourland's testimony, St. Jude would have been entitled to judgment as a matter of law finding that neither patent had been infringed.

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[34] This motion comes before the court on Docket Nos. 818, 819, 820, 821, 825, 832, 833, 836, 837, 846, 847, 859, 862, 878, 882, 883, and 885. The relevant evidence has been submitted in writing. No party has requested an evidentiary hearing on the motion. The depositions cited regarding this issue were not introduced as evidence at trial but have been submitted only on this issue.

In pretrial reports and in the briefing on motions for summary judgment, Dr. Bourland also considered and addressed issues of validity, including obviousness and the written description requirement as applied to the '472 patent. At trial, however, CPI chose not to ask him about obviousness issues.

While Dr. Bourland was working for CPI on this case, he was also working as an expert witness for the third principal ICD manufacturer, Medtronic, in another case called *Moore v. Medtronic*. Dr. Moore sued Medtronic for royalty payments allegedly due under a license agreement concerning other ICD patents. In his work for Medtronic, Dr. Bourland prepared a report addressing issues of patent infringement and validity on issues closely related to those presented here. *See* Ex. 4051.

When Dr. Bourland's report in the *Moore* case came to light, it became apparent that his approaches to and opinions about some of the same patents (such as Engle '614 and Engle '817) and nearly identical issues in this case and the *Moore* case were very different.

B. Dr. Bourland's Deception

The specific issue that caused the trouble was Dr. Bourland's testimony about the extent of other work he had done as an expert witness. The undisputed evidence, including Dr. Bourland's own testimony in a post-trial deposition, establishes that Dr. Bourland deliberately lied during his pretrial deposition and during his trial testimony in this case, and in a post-trial affidavit. Plaintiffs themselves concede: "Plaintiffs do not seek to excuse or minimize Dr. Bourland's actions." Docket No. 846 at 1. Dr. Bourland's sworn testimony before, during, and after trial was deliberately false.

1. Dr. Bourland's Deception Before Trial

Dr. Bourland gave his pretrial deposition in this case on March 24, 2001. He volunteered that he had been "involved

in some litigation within the last five years that involves some Medtronic devices." Bourland Pretrial Dep. at 38. He was asked what litigation it was. He answered: "There were actually two suits that were involved and both of those have now been resolved." The testimony continued:

> Q And who was the litigation involving Medtronic against?
>
> A There was one that was in the case of *Charms versus Medtronic*. And there was a second one in the case *Moore versus Medtronic*. But I was not an expert—did not go to the point of having depositions taken in that.
>
> A Did you provide any expert reports?
>
> Q Don't believe we got that far.

Bourland Pretrial Dep. at 38. The last answer was false. When he gave this deposition testimony in this case, Dr. Bourland had completed two expert reports in the *Moore* case that had already been provided to opposing counsel in that case.

After the trial in this case, Dr. Bourland explained that when he gave his pretrial deposition, he had not merely "forgotten" about those reports:

> Q Was your answer false?
>
> A It was false, and the reason was, I felt it would have been a violation of confidence to reveal what was going on in the case A to attorneys in case B.
>
> Q Okay. Meaning that, your answer was not mistaken, it was deliberate based on your understanding of the confidentiality order?
>
> A I was very reluctant to share the proceedings in one case with another. And the answer

> is yes, I did not feel I should answer that question and reveal what was going on in the other case.
>
> * * *
>
> Q Do you believe that your confidentiality obligation requires you to lie under oath?
>
> A I do not.
>
> Q But that's what you did, isn't it?
>
> A I was faced with a moral dilemma, and that is, I violate one obligation or I violate the other. And I chose to not reveal what was going on in a case that was in potential competition to the one underway.

Bourland Post-trial Dep. at 37-38, 39-40.

This "moral dilemma," however, had obviously not prevented Dr. Bourland from at least telling CPI's and St. Jude's lawyers about the existence of the cases. Why the mere existence of the reports should be so sensitive is something Dr. Bourland has not explained.[35]

The evidence thus demonstrates that Dr. Bourland made a deliberate decision during his pretrial deposition in this

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[35] After studying Dr. Bourland's principal report in the *Moore* case, the court sees no legitimate basis for a court to treat it as confidential at all. *See generally Union Oil Co. of California v. Leavell*, 220 F.3d 562, 567-68 (7th Cir. 2000) (discussing circumstances in which court may properly seal records). Dr. Bourland discussed a number of patents and prior art—all of which were public documents—and reported on the results of his examination of Medtronic devices that were available on the market for sale, scrutiny, and even reverse engineering.

case to lie rather than disclose the truth about his work in *Moore v. Medtronic*. CPI points out that Dr. Bourland and CPI were not required by Fed. R. Civ. P. 26(a)(2) to disclose the fact of his work in the *Moore* case, let alone the report itself. For hired experts, the rule requires a listing of cases in which the witness has given trial or deposition testimony. It does not mandate such a listing of all cases in which the expert has consulted or provided a report. At the risk of emphasizing the obvious, however, those limits on Rule 26(a)(2) cannot possibly excuse a deliberate decision to give a false answer to a direct question in a deposition.[36]

2. Dr. Bourland's Deception During Trial

During the afternoon of June 14, 2001, Dr. Bourland was being introduced to the jury. He gave the following testimony:

> Q Now, Dr. Bourland, you're here to testify as an expert witness in this lawsuit now, correct?
>
> A That is correct.
>
> Q Have you ever been an expert witness before?

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[36] Dr. Bourland testified in the pretrial deposition that he believed the *Moore* case had been resolved. He later testified that his belief was based on a telephone call he had received from Medtronic's attorneys in the case. Before trial in this case, however, Dr. Bourland learned that the *Moore* case had not been resolved. In May and early June 2001, he was preparing for his deposition in the *Moore* case, in addition to preparing for trial in this case. Dr. Bourland did not correct this mistake, either when he had an opportunity to review his deposition testimony or later.

> A One time many, many, years ago, but it was not a patent infringement suit.
>
> Q So you don't do this for a living?
>
> A No, sir. I certainly do not.

Tr. 757. The obvious intent and effect of this testimony was to present Dr. Bourland as an intellectually honest academic rather than a professional expert witness. Dr. Bourland then began explaining why, in his view, St. Jude's devices infringed the '472 and '288 patents. His direct examination was not complete when the court recessed for the evening.

Listening in the courtroom audience that afternoon was an attorney for Dr. Moore in *Moore v. Medtronic*. After the court recessed, Dr. Moore's lawyer spoke with counsel for St. Jude and provided a copy of an expert witness report that Dr. Bourland had written in the *Moore* case.

The next morning, before Dr. Bourland had completed his direct examination, counsel for St. Jude provided a copy of the *Moore* report to CPI's counsel and stated their intent to use the report in their cross-examination. As a result, neither Dr. Bourland nor CPI's counsel were surprised when the report was used in cross-examination. During cross-examination, Dr. Bourland was asked:

> Q Did you overlook a more recent case in which you were retained as an expert witness?
>
> A Actually, no. When he asked the question, I thought he asked me had I been in court as an expert witness, and so I must have misunderstood the question. I apologize if I misled you.
>
> Q I thought that's what had happened.

Tr. 1011. That explanation appeared to be plausible at the time, for CPI's question on direct about whether he had been

"an expert witness" had not been precise. CPI's counsel had already suggested the "forgetfulness" explanation during discussion of the proposed exhibit before Dr. Bourland took the stand the morning of June 15th. Tr. 907.

After trial, however, Dr. Bourland confessed that this benign explanation was false:

> A * * * Prior to trial, I very much limited my conversation to [CPI's attorneys] about the other lawsuit, because I thought that would be a violation of the confidentiality agreement that I had in—involving those suits.
>
> Q Was that the reason you did not mention the *Moore* or the *Charms* case in your direct testimony at trial?
>
> A That is correct.
>
> Q So you didn't forget that you were involved in the *Moore* and the *Charms* case on the 14th of June, did you?
>
> A I felt like I would be violating a confidence if I discussed one area of litigation in the context of the other. I thought that would be a violation of an agreement that I had made with the other court.
>
> Q I understand. My point is, that you didn't forget about the *Moore* case or the *Charms* case, you chose not to reveal them because of what you thought was your obligation under the confidentiality order, correct?
>
> A That is correct.

Bourland Post-trial Dep. at 30-31. In addition, Dr. Bourland also later admitted that in the one case he did mention during his direct trial testimony, he had never testified in court. *Id.*

at 21-23. Thus, Dr. Bourland's explanation on cross-examination, which CPI has continued to advocate long after Dr. Bourland himself had abandoned it—that he had "misunderstood" the question from CPI's lawyer—was thoroughly false. *Cf.* Docket No. 846 at 17-18.

It is now as plain as could be that Dr. Bourland did not merely forget the *Moore* case or the report when he testified on direct. He made a deliberate decision not to answer truthfully. Then, when confronted on cross-examination, he deliberately offered a false excuse for the supposed "misunderstanding" on direct.

Moreover, Dr. Bourland's professed concern about his obligations under other protective orders is of dubious credibility. He never bothered to check his views on this "moral dilemma" by, for example, actually checking the protective orders or consulting a lawyer. *See* Bourland Post-trial Dep. at 40, 45-50. If his professed concern were deemed credible, it might be of interest to other authorities who have responsibility for dealing with perjury, such as federal prosecutors. But whether Dr. Bourland's asserted but ill-considered excuse is honest or not has no bearing on this case or the prejudice his action caused to St. Jude or to the integrity of this proceeding.[37]

3. Dr. Bourland's Deception After Trial

When the jury returned its verdict, the major damage was done but Dr. Bourland's deception continued. St. Jude

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[37] In the event of a genuine conflict between a protective order and a witness's obligation to testify in another case, of course, the conflict may be raised with the courts in question and a resolution will be found. Dr. Bourland's self-help method for resolving his professed "moral dilemma" has nothing to recommend it.

sought and was granted permission to conduct post-trial discovery with Dr. Bourland regarding his actions and testimony. In response to a request to take Dr. Bourland's deposition, CPI's counsel helped Dr. Bourland prepare an affidavit that he signed on July 11, 2001. Docket No. 809. That affidavit was not a successful effort to be honest.

In Paragraph 4, Dr. Bourland explained his failure to disclose the *Moore* reports during his deposition on the ground that he thought the question had applied to the *Charms* case and not to the *Moore* case. That is not how the transcript reads, though it is not unusual for witnesses to misunderstand questions. When questioned in the July 18th deposition, Dr. Bourland repeated that explanation at first. When asked again, however, he abandoned the "misunderstanding" explanation:

> Q And in the *Moore* case, you prepared, as of March 24th, two reports?
>
> A Yes, I have.
>
> Q Was your answer false?
>
> A It was false, and the reason was, I felt it would have been a violation of confidence to reveal what was going on in the case A to attorneys in case B.

Bourland Post-trial Dep. at 37. Thus, when pressed even mildly, Dr. Bourland did not claim to have misunderstood the question as limited to the *Charms* case. The explanation that he and CPI's lawyers provided in the post-trial affidavit collapsed just a week after they offered it under oath.

Perhaps most striking in the affidavit is its concluding assertion: "At no time did I ever intend to conceal the fact that I had prepared expert reports in the *Moore* case and had served as an expert in that matter during the pendency of this case." Paragraph 7. Dr. Bourland admitted during his depo-

sition taken just one week later, on July 18th, that he had in fact intended to conceal both the report and his work in the *Moore* case. Bourland Post-trial Dep. at 30-31 (quoted above). Paragraph 7 is also plainly false.

C. The Effects of Dr. Bourland's Deception

Dr. Bourland's false testimony assisted him and CPI in two principal ways. The overall effect was to deny St. Jude a fair trial and to undermine the integrity of this proceeding.

First and most basic, Dr. Bourland's false direct testimony enabled CPI to present Dr. Bourland to the jury as more of an honest academic researcher than as a "hired gun" expert witness. That deceptive presentation helped enhance Dr. Bourland's credibility before the jury. After trial, however, Dr. Bourland also testified that, despite his testimony that he does not testify as an expert for a living, income from such work was "a substantial amount" of his earned income for the year 2000. Bourland Post-trial Dep. at 150.

The second form of assistance is both more important and more complex. CPI's infringement theories in this case required some long (too long) intellectual stretches. It was up to Dr. Bourland to do the stretching and to convince the jury to follow him. The same can be said of CPI's approach to the written description issue under the '472 patent.

Regarding the determining means element in the '288 patent claims, CPI and Dr. Bourland had to argue that the relatively sophisticated "binning" algorithm in St. Jude's ICDs was equivalent to the determining means described in the '288 patent, which combined the use of a cardiac rate detector with the so-called "probability density function" (PDF) detector. The two types of devices performed the same general function—any ICD must have some mechanism for detecting the heart's rhythm and determining when therapy is needed. It was up to Dr. Bourland to convince the jury that these different means for accomplishing that function were

equivalent to one another. On that issue, Dr. Bourland apparently was not successful. The jury found that the '288 patent was not infringed.

Dr. Bourland was more successful with the '472 patent. His testimony laid the essential foundation for the jury's verdict awarding CPI $140 million. He provided the testimony, for example, that the more sophisticated "H-bridge" switches in St. Jude's products were equivalent to the simpler "switch means" disclosed in '472 patent. Tr. 855. He also provided essential testimony to support CPI's theory that the software or "firmware" programmed into the St. Jude devices was equivalent to the "initiating means" disclosed in the '472 patent. Tr. 873-74. Dr. Bourland's testimony was essential to allow CPI to avoid judgment as a matter of law on infringement of the '472 patent.

Dr. Bourland's report in the *Moore* case offered an extensive basis for impeaching his testimony in this case. It also offered an extensive basis for attacking CPI's defense of the validity of the '472 and '288 patents.

Dr. Bourland testified in this case that St. Jude's determining means were equivalent to the rate-plus-PDF determining means in the '288 patent even though the rate-plus-PDF system was less reliable, resulting in more unnecessary shocks for the patient. He testified that rate-plus-PDF was interchangeable with rate-only. Tr. 783, 795. He also testified on cross-examination that the use of rate-plus-PDF resulted in unnecessary shocks to patients. Tr. 957. He added that the change away from use of PDF "dramatically reduced" the incidence of unnecessary shocks. *Id.* A moment later, though, apparently after realizing the effect of that concession, he back-pedaled and claimed there was no "dramatic difference." *Id.* at 957-58.

Dr. Bourland eventually agreed "that the use of rate alone, as St. Jude uses rate, gives many fewer shocks than the use of PDF alone, or the use of PDF with rate." Tr. 959.

Nevertheless, he still did his best to minimize the different results. *See* Tr. 963-66. He even went to the impossible length of asserting that, as long as the two types of devices both identify arrhythmias, the reliability of their results has nothing to do with the patent issues. Tr. 965. (The court's Final Instruction Nos. 35 and 36 were to the contrary, teaching that the relevant "result" of the determining means was "the accuracy and reliability with which arrhythmias are diagnosed, leading to delivery of the correct therapy at the correct time.") Even a 10 percent difference in reliability of the results, Dr. Bourland said, did not prevent the different determining means from producing "substantially the same result." Tr. 966.[38]

In other words, Dr. Bourland struggled on the witness stand to portray St. Jude's rate-only binning algorithm as an equivalent of the '288 patent's less reliable determining means with rate-plus-PDF. The jury did not buy this testimony. But in light of its finding of infringement of the '472 patent, the jury obviously did not reject Dr. Bourland as an outright liar who was willing to say almost anything to help CPI win.

With full use of the *Moore* report, Dr. Bourland's efforts would have appeared very different. In his *Moore* report, Dr. Bourland took an opposite approach to the results generated by different detecting means. He was examining the Engle

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[38] When Dr. Bourland testified about a 10 percent difference, he was testifying about 10 percent of all patients with an implanted device. Thus, he meant a difference such as between a 25 percent rate and a 15 percent rate of unnecessary shocks, not a difference such as between a 22 percent rate and a 20 percent rate, which could also be called a "10 percent" difference between those two rates. *See* Tr. 965.

'614 patent and the Engle '817 patent, which taught determining means that shocked a patient in response to the first very short interval between two ventricular contractions (the "R-R interval," referring to the "R" portion of a display of the voltage of a typical heartbeat).

In response to an equivalence argument by plaintiff in the *Moore* case, Dr. Bourland argued there was no equivalence because the '614 and '817 devices "would frequently cause therapy to be delivered unnecessarily." Ex. 4051 at 26. The result would be unnecessary pain for the patient and a significantly shorter battery life. Dr. Bourland opined that Medtronic's algorithm, which required at least two consecutive short R-R intervals was "substantially different from" and "not interchangeable with" the determining means of the '614 and '817 patents. *Id.* at 27.

Thus, in the *Moore* case, Dr. Bourland took a far narrower approach to a very similar equivalence problem involving the means used in ICDs to identify an arrhythmia and the appropriate electrical therapy. In contrast to his testimony in this case, he opined in *Moore* that the reliability of the determining means' results was critical to equivalence.

In addition, Dr. Bourland's *Moore* report casts a different light on the obviousness issue concerning the multimode therapy claimed by the '288 patent. In the *Moore* report, Dr. Bourland addressed not only the Engle '614 patent, but also Denniston '795 and Zacouto '399, which were addressed in this case. *See* above, Part VII. Dr. Bourland came very close to asserting that Denniston and Zacouto showed multimode therapies: "The idea of successive electrical stimulus therapies being delivered at increasing energy levels is shown in U.S. Patent No. 3,805,795 to Denniston et al." Ex. 4051 at 8. He later added: "The idea of detecting a progression of ventricular tachyarrhythmia and delivering repetitive therapy pulses was not invented by Dr. Moore. As discussed above, prior art references to the '614 and '817 patents disclose

these concepts, for example, the Denniston et al. '795 patent and the Zacouto '399 and '991 patents." Ex. 4051 at 34.

In this case, moreover, there was a major dispute over whether Denniston '795 disclosed "cardioversion" as one of the multiple modes available. As discussed above in Part VII B regarding obviousness, the issue is important for the validity of Claims 4 and 13 of the '288 patent, which require that cardioversion be one of the multiple modes.

In his *Moore* report, Dr. Bourland stated: "The [Denniston] '795 patent shows successive *cardioverting* shocks with the output capacitor charged to 700 and 900 volts, respectively. Also, U.S. Patent Nos. 3,857,399 and 4,052,991 to Zacouto show a stimulation pulse that is increased when the interval of time between systoles is smaller." Ex. 4051 at 8-9 (emphasis added). These conclusions flatly contradict CPI's approach to the same patents in this case.

More generally, on the issue of equivalence, Dr. Bourland's testimony in this case repeatedly took the simplistic approach that, as long as a St. Jude device contained structure that performed the same function as the claimed means in the '472 or '288 patents, the St. Jude device contained equivalent structure. In the *Moore* report, Dr. Bourland was far more discriminating. He recognized in that report that merely performing the same function was not sufficient, and he went on to analyze the way and result elements of the most familiar "function-way-result" approach to analyzing equivalence issues. Ex. 4051 at 25-30.

The court said at trial that timely disclosure of the *Moore* report would have been very helpful to St. Jude and probably would have enabled "very effective" cross-examination of Dr. Bourland on the equivalence issue. Tr. 2764. The court stands by that view.

In an attempt to minimize the effects of Dr. Bourland's deception, CPI points out that St. Jude did in fact obtain a

copy of Dr. Bourland's expert report in the *Moore* case at the end of his first day of testimony and then did relatively little with it in cross-examining him. The point is factually correct but misses the actual effects.

First, St. Jude was expecting Dr. Bourland to testify on issues of validity as well as issues of infringement. At the end of the first day of Dr. Bourland's testimony, the St. Jude lawyer who would cross-examine him learned for the first time that Dr. Bourland would not be addressing validity issues. *See* Tr. 899. That attorney had to spend that night restructuring and reorganizing his planned cross-examination of Dr. Bourland. It simply is not realistic in a case of this complexity to expect attorney Rackman both to have done that essential work and to have digested a 35-page expert report and planned a cross-examination using the report. That is why Rule 26 of the Federal Rules of Civil Procedure requires so much advance disclosure of expert materials. Those reasons apply with great force in a high-stakes patent case.

Second, the issues are complex. As talented as all the lawyers in this case are, digesting the *Moore* report and preparing to use it effectively before a jury would have taken much more time than Rackman had, especially with a witness as smart as Dr. Bourland, and especially without an opportunity to take his deposition to ask detailed questions about the report. CPI's lawyers themselves made this point about the complexity of the issues in explaining their failure to raise during trial any of the objections they first made after trial to St. Jude's demonstrative exhibits addressing Dr. Bourland's contradictions. Docket No. 841 at 18 n. 4.

CPI also argues that defendants "misrepresented" the content of Dr. Bourland's report from the *Moore* case. (CPI even made that charge its heading in its brief, Docket No. 846 at 13.) It is not wise for CPI to make that charge in this case. The court disagrees in any event, as explained below

with respect to CPI's own motion for a new trial on the '288 claims.[39]

D. The Role and Responsibility of CPI and its Lawyers

The foregoing discussion shows that Dr. Bourland deceived the jury, deceived the court, and deceived St. Jude. He did so deliberately, and he did so on matters that go to the heart of the case and to the heart of his credibility. In determining what to do about Dr. Bourland's deception, the court must also consider what CPI and its lawyers knew about Dr. Bourland's deception and when they knew it.

The morning of June 15th, CPI attorney Sherry told the court that St. Jude's counsel had just informed him that St. Jude intended to use Dr. Bourland's report from the *Moore* case (Ex. 4051) in their cross-examination of Dr. Bourland. Sherry objected to the "surprise and ambush," stating: "We have no information about that lawsuit or about this expert report . . . ." Tr. 905. At the very least, that was an unwise exaggeration.

When CPI's lawyers first interviewed Dr. Bourland about working on this case, he told them that he had worked on an unidentified "royalty" case. Bourland Post-trial Dep.

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[39] To the extent the evidence regarding Dr. Bourland might be minimized as "only" impeachment evidence, such a description is not completely accurate. In any event, a fair opportunity to impeach such a critical witness is central to the just resolution of this case. *See United States v. Shaffer Equipment Co.*, 11 F.3d 450, 460-61 (4th Cir. 1993) (ordering district court to consider ordering only a new trial rather than dismissal where plaintiff failed to disclose key expert's falsification of his credentials and thus precluded impeachment).

at 26. There is no indication that the attorneys on CPI's trial team in this case knew anything more about the *Moore* case until Dr. Bourland's deposition on March 24, 2001, when he disclosed the fact that he had worked on the case (and claimed that it had been "resolved"). Bourland Pretrial Dep. at 38.

After that deposition and before trial, though, CPI and its lawyers learned a great deal more about the *Moore* case. Dr. Moore had filed a similar royalty claim against CPI and Guidant on February 28, 2001. The evidence now shows that CPI and Guidant had entered into a joint defense agreement with Medtronic regarding the *Moore* case. On March 30th, less than a week after Dr. Bourland's deposition testimony in this case to the effect that *Moore* was resolved and that he had not prepared a report in it, lawyers for Medtronic met with CPI's inside lawyers—Richard Clapp and Ralph Hall—to discuss their joint defense of the *Moore* cases.

At that meeting, Medtronic's lawyers gave Clapp files containing Dr. Bourland's two reports in the *Moore* case. Forneris Answers to Written Dep. Questions ¶ 5; Eisenberg Answers to Written Dep. Questions ¶ 5; Clapp Dep. on Written Questions ¶¶ 1-3. Clapp reviewed the Bourland report sometime in May 2001. Clapp Aff. ¶ 10.[40]

Ralph Hall is the inside attorney for CPI and Guidant who has had principal responsibility for this case. Hall's official position was vice president and general counsel of

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[40] CPI and Guidant had also entered into a joint defense agreement with Medtronic regarding the *Charms* case, in which Dr. Bourland also prepared a draft expert report that was never submitted to opposing counsel. The draft *Charms* report also was not disclosed until the post-verdict discovery and motion practice in this case.

Guidant's Cardiac Rhythm Management Group. He testified at trial in this case and was actively engaged in supervising the outside counsel. During virtually the entire trial, he sat at counsel table as CPI's representative.

Hall remembers the March 30th meeting but denies recollection of any mention of Dr. Bourland or his report in the meeting on March 30th: "I don't deny the accounts given by Medtronic's counsel; I simply do not have any recollection of the brief exchange to which they attest." Supp. Dec. of Hall ¶ 4. Hall also denies ever reviewing the materials turned over by Medtronic's lawyers; he says that his colleague Clapp kept them.

With respect to CPI's trial attorneys in this case, the evidence shows that at least Sherry and Surrette were well aware of the *Moore* case before trial in this case. Although there is some conflict on the point, it now appears that both Sherry and Surrette attended Dr. Bourland's deposition in this case. Surrette Dep. on Written Questions ¶ 1. (Hall did not attend, and he denies having ever reviewed Dr. Bourland's deposition transcript before trial.) The attorneys in the *Moore* case had scheduled Dr. Bourland for a deposition in early June 2001. CPI's attorneys in this case learned of that deposition on June 1st when they were preparing Dr. Bourland to testify in the June trial in this case. Surrette Dep. on Written Questions ¶ 2. They sought and obtained permission from CPI attorney Clapp to reschedule Dr. Bourland's deposition in the *Moore* case. Sherry Dep. on Written Questions ¶ 11. That was just two weeks before Sherry, to support his claim of "surprise and ambush," told the court: "We have no information about that lawsuit or about this expert report . . . ."

When they delayed Dr. Bourland's deposition, Sherry and Surrette both had the information they needed to realize that Dr. Bourland's deposition testimony had not been accurate when he told St. Jude's attorney that the *Moore* case had been resolved and that he had not prepared an expert report

in *Moore*. When the court later asked CPI's counsel about this, the response was that the attorneys did not "put the two things together" or know that there was a report. Tr. 2555; *see also* Tr. 2562-63 (Sherry stating he first learned of the *Moore* report on June 15th; "it never entered my mind that there was anything other than a scheduling conflict there"). Sherry and Surrette have stood by that account in their post-trial testimony. *See* Sherry Dep. on Written Questions ¶¶ 1, 3, and 10 (first learned of existence of report on June 15); Surrette Dep. on Written Questions ¶ 1.

Accepting as truthful all testimony from CPI lawyers and testimony from Dr. Bourland about his contacts with those lawyers, it is plain that when the knowledge of different CPI lawyers is viewed collectively, CPI knew at the time of Dr. Bourland's trial testimony that it was false. Attorney Sherry—who defended Dr. Bourland's March 24th deposition and who conducted his direct examination at trial--knew of the *Moore* case and Dr. Bourland's work on it. He should have known that Dr. Bourland had prepared at least one expert report (in fact, it was three by the time of trial). Attorney Surrette also knew of those points. Attorney Clapp knew of Dr. Bourland's work on the *Moore* case and actually had a copy of Dr. Bourland's report—the one discussing several of the same prior art patents and issues nearly identical to those at issue in this case. Hall's denial of such knowledge depends on whether his March 30th telephone call occurred while Medtronic lawyers were talking about Dr. Bourland with Clapp and giving him the report. Attorneys Sherry, Surrette, and Clapp all knew that the *Moore* case had not been resolved.

CPI's excuse for this situation is that no single individual actually put all this information together—that Sherry and Surrette simply failed to recognize the conflict, and that Clapp did not know enough about this case to make use of his possession of the *Moore* report. The court cannot and

does not find by a preponderance of the evidence that the excuse regarding these attorneys was false. The failure to recognize Dr. Bourland's deception presumably would save any individual attorney from any responsibility for those early deliberate deceptions of the court and St. Jude. However, those individual failures do not excuse what amounts to CPI's collective negligence in failing to recognize Dr. Bourland's deception and its attorneys' failure to correct before the trial ended the misimpressions they had given the court.

The failures of CPI's attorneys continued after Dr. Bourland left the witness stand. After St. Jude filed on June 25th its motion to strike Dr. Bourland's testimony, CPI's attorneys began scrambling to find out more about the situation. Hall called Clapp and learned on June 25th or 26th that Clapp had been given a copy of Dr. Bourland's report in the *Moore* case. Hall Dep. on Written Questions ¶ 5. Hall was present in court on June 27th when attorney Malloy asked the court to inform the jury that he had not been aware of the report before June 15th. Without thinking that Malloy's request was limited to his own personal knowledge (as opposed to the knowledge of Hall or anyone else at counsel table), the court responded: "I will add there was no indication that CPI's counsel had the report before trial." *See* Tr. 2885 (emphasis added).

The court believes that Hall had an obligation to correct that false impression, or at the very least to raise the ambiguity presented by the fact that Clapp, CPI's chief patent counsel, had possessed the Bourland report since March 30th. Hall had learned that fact one or two days earlier. In court, he remained silent. His silence allowed the court to give the jury what Hall should have realized was a false impression that tended to minimize the responsibility of CPI and its attorneys.

Malloy has testified that Hall told him "some time during the last week of trial (I do not recall which day)" that

CPI's Clapp had a copy of the *Moore* report. Malloy Dep. on Written Questions ¶ 7. Sherry also learned this fact from Hall but does not recall when. Sherry Dep. on Written Questions ¶ 7. The court finds it is most likely that Hall informed Malloy and/or Sherry as soon as possible about the fact that Clapp had a copy of the Bourland report in *Moore*. In any event, whenever they learned that Clapp had the report, neither Malloy nor Sherry ever informed the court about Clapp's possession of the report until the post-trial briefing. The court believes CPI's lawyers had an obligation to inform the court of that fact before the end of the trial, especially in light of the court's comments made at Malloy's request.[41]

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[41] There was one other dispute over sharing information with the court. About midnight on June 26th (the end of the day of June 26th), CPI attorney McCaulley received a telephone call from Dr. Bourland responding to Sherry's urgent message of the 25th. Dr. Bourland told McCaulley that he would return to Indiana late the next day, June 27th. June 27th was the day the court acted on St. Jude's motion and told the jury that Dr. Bourland was traveling and not available to return to deal with these issues directly. Tr. 2890. McCaulley told some other members of the CPI trial team, but he does not recall who or when. McCaulley Dep. on Written Questions ¶ 1. Sherry says he did not know of this information the morning of June 27th, but he was not more specific about later in the day, which is relevant because the court did not act to inform the jury until the afternoon.

CPI's attorneys did not inform St. Jude's attorneys or the court that Dr. Bourland would be available for recall to the stand before the end of trial. The court must presume that their failure to share that information, whether before or after the court's statements to the jury on June 27th, was a deliberate choice. That choice is a strong indicator that, contrary to the posi-tions CPI has taken in its post-trial briefs, *see, e.g.*, Docket No. 846 at 2, CPI did not want

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Thus, the evidence shows that CPI and its attorneys were at least negligent in failing to recognize and correct Dr. Bourland's deception. Once the problem came to light, they also did not promptly share with the court or St. Jude their knowledge about this troubling situation, leaving the critical details instead to be extracted slowly through post-trial discovery conducted by St. Jude, and not admitting CPI's possession of the *Moore* report—which Hall and Malloy, and apparently Sherry, all knew about before trial ended.

E. The Appropriate Consequences

As St. Jude wrote in its reply brief: "Through all of the smoke, one crucial fact remains clear: Plaintiffs' principal expert witness on both patents at issue, deliberately and repeatedly failed to tell the truth." Docket No. 862 at 2. What should be the consequences of Dr. Bourland's intentional deception and the failure of CPI and its lawyers to correct the deception?

St. Jude seeks an order striking Dr. Bourland's testimony from the trial evidence. St. Jude argues that the court should then decide all its post-trial motions based on the record minus Dr. Bourland. That approach would call for judgment as a matter of law for St. Jude on all infringement claims. In the alternative, St. Jude seeks a new trial on all issues upon which it did not prevail at trial, together with monetary sanc-

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Dr. Bourland to be anywhere near this court or its witness stand for the rest of the trial. CPI's criticism of St. Jude for not inquiring into Dr. Bourland's schedule, *see* Docket No. 846 at 7-8 n.4, is a classic case of blaming the victim, especially in view of CPI's own continuing silence on the question *even after CPI's trial counsel knew that Dr. Bourland had returned to Indiana.*

tions. CPI argues that the court has already done enough—in fact, CPI contends the court did too much, and that the court's and St. Jude's actions during trial should entitle CPI to a new trial on the '288 patent.

1. Remedial Steps Taken at Trial

On the eleventh day of trial, St. Jude filed a motion seeking sanctions for Dr. Bourland's testimony. Docket Nos. 769 & 770; Tr. 2456-57. St. Jude first sought to introduce as evidence in this case Dr. Bourland's expert witness report in *Moore v. Medtronic*. CPI eventually decided not to object to that relief, and the report was admitted as Exhibit 4051. Tr. 2762; 2883.

St. Jude also argued that it would be appropriate for the court to strike Dr. Bourland's testimony in whole or in part, or to instruct the jury that, in light of his misleading statements, his testimony could be disregarded. St. Jude also argued that its own experts should be allowed "considerable leeway" in discussing Dr. Bourland's report from the *Moore* case for the light it shed on issues of infringement and validity in this case.

The court decided that the appropriate action during the trial was to inform the jury of the relevant chronology (to the extent it was then known) and to allow the defense to display and/or read aloud to the jury excerpts of Dr. Bourland's trial testimony in this case and the contrasting portions of the report from the *Moore* case. Tr. 2765-66. When the court made its decision, the court did not know that Dr. Bourland had deliberately chosen to lie during both his deposition and during his testimony in court. At that time, "forgetfulness" still appeared to be a plausible explanation for Dr. Bourland's testimony. The court also did not have before it the much more extensive record that was developed on this issue after trial, including, for example, the fact that on March 30, 2001, Medtronic lawyers had given CPI's inside lawyers a copy of Dr. Bourland's report from the *Moore* case.

The court's actions appear in the trial transcript at page 2888 and following, on Wednesday, June 27, 2001. The court quoted for the jury Dr. Bourland's deposition testimony in which he denied having prepared any expert reports in the *Moore* case. The court then stated: "The report that Dr. Bourland prepared in that case should have been disclosed by Dr. Bourland and CPI to the defendants in this case well before trial. There is, however, no indication that CPI's counsel had the report before trial." Tr. 2890. The court explained that Dr. Bourland was then on a long-scheduled trip and was not available to address these matters directly. The court instructed the jury that they could consider these matters along with "all the other evidence in evaluating Dr. Bourland's credibility, that is the credibility of all of Dr. Bourland's testimony." Tr. 2890-91.

The defense then displayed to the jury demonstrative exhibits 8600, 8600-1, and 8601 and read them aloud, with enough of an explanatory gloss to draw objections from CPI and the court. Tr. 2891-95. The demonstrative exhibits (which were not given to the jury for their deliberations) displayed the contradictions between Dr. Bourland's positions in the two cases.

During closing arguments to the jury, St. Jude emphasized the actions the court had taken and the inconsistencies between Dr. Bourland's positions in the two cases. Tr. 3413-17. CPI attorney Malloy told the jury that Dr. Bourland had forgotten the *Moore* case. Malloy continued:

> We weren't involved in that, not going to excuse to say I'm not in that case. But he had a report in another case that dealt with the Engle patent. And he had testified back in March or thereabouts did he have a report he said no. It turned out it wasn't accurate. He should have said yes.

> I'm going to tell you, just like [St. Jude witnesses] Dr. Rickards and Dr. Mihran, he forgot.

Tr. 3373 (emphasis added). Malloy went on to compare Dr. Bourland's "forgetfulness" to errors made by St. Jude's expert witnesses in which they admitted during cross-examination that they had forgotten some points. Tr. 3373-75.[42]

Malloy's device apparently worked. The jury could not have found St. Jude liable for infringing the '472 patent without crediting Dr. Bourland as a witness to a substantial degree.

We all now know that this "forgetfulness" explanation was false. We also know that Dr. Bourland never told CPI's lawyers that he had "forgotten." Bourland Post-trial Dep. at 79. It is difficult to believe the jury could have given Dr. Bourland any credit at all if they had known that he did not forget, but instead made a deliberate decision to conceal what he had done in the *Moore* case.

In light of what is now known about Dr. Bourland's actions, the court is now convinced that the remedial actions taken at trial were not sufficient and were not effective to cure the prejudice caused by Dr. Bourland's deception. The jury was entitled to know not only that Dr. Bourland had contradicted himself on several matters at the core of this case, but also that he had deliberately lied in such a way as to prevent the disclosure of those contradictions.

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[42] CPI points out that St. Jude did not object to this argument. At the time, St. Jude did not know that Dr. Bourland had not merely forgotten but had instead deliberately decided not to tell the truth in his deposition and at trial.

In the court's experience, for most jurors who must evaluate the credibility of witnesses, the difference between forgetfulness and deliberate deception is a wide chasm. That chasm remains wide even if one accepts Dr. Bourland's July 18th explanation for his deceit. And especially where the conflicting testimony of the witnesses addresses very difficult technical matters, as here, a juror's trust or confidence in a witness's honesty can be critical. The court's Final Instruction No. 8 included the following standard language reflecting this difference: "If you believe a witness has knowingly testified falsely about any significant matter, you have a right to distrust that witness's testimony on other matters, and you may reject all the testimony of that witness or give it such weight as you think it deserves."

2. Appropriate Sanctions After the Trial

At trial, the court told counsel that the actions being taken during trial were not necessarily the last word on the subject: "The Bourland situation, frankly, casts a cloud over any potential plaintiffs' verdict that might result in this case." Tr. 2765. The court also stated that if the situation forced a retrial, "I will certainly consider the possibility of substantial financial sanctions." *Id.* In light of what is now known, it is clear that further sanctions are needed to remedy the effects of Dr. Bourland's deception.[43]

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[43] This knowledge distinguishes this case from *Ryder v. City of Topeka*, 814 F.2d 1412, 1424-27 (10th Cir. 1987), upon which CPI relies. In *Ryder* the appellate court affirmed denial of a new trial where a key defense witness's prior statement was not produced before trial. The statement was produced during trial and was used by the plaintiff against a witness who remained available throughout the trial. The district court had found that the plaintiff's opportunity to use the statement was sufficient to avoid prejudice. In

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St. Jude first requests an order striking Dr. Bourland's testimony from the trial record, so that all other post-trial motions would be decided without considering his testimony. For this sanction, St. Jude relies on Rule 37(c)(1) of the Federal Rules of Civil Procedure, which provides in relevant part: "A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions," which may include "requiring payment of reasonable expenses, including attorney's fees, caused by the failure."

CPI argues that Rule 37(c)(1) does not apply because there was no failure to comply with its terms. Rule 26(a)(2) did not require Dr. Bourland and CPI to disclose his *Moore* report before the deposition in this case. Rule 26(a)(2) does not require an expert's report to disclose other cases in which he has merely consulted and prepared a report, but without having testified in a deposition or trial.

When Dr. Bourland was asked in his deposition about such reports, however, he was not entitled to lie to deny their existence, as he did. CPI and Dr. Bourland violated Rule 26(e)(1), which imposes a duty to supplement discovery responses. With respect to hired expert witnesses, "the duty extends both to information contained in the report and to information provided through a deposition of the expert."

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this case, St. Jude and the court did not learn until after the trial that Dr. Bourland lied deliberately. Also, because of the complexity of the subject matter, effective use on short notice was difficult.

Even if Dr. Bourland's false testimony in his deposition had been unintentional, that duty to supplement required Dr. Bourland and CPI to correct the wrong information he had provided in his deposition about the *Moore* case and his work in it.

CPI tries to avoid Rule 26(e)(1) on the theory that it did not know about Dr. Bourland's deposition testimony was incomplete or incorrect. The evidence developed after trial shows, however, that CPI as an entity with many lawyers had all the information it needed to recognize that Dr. Bourland's deposition testimony about his prior expert work was, in the language of the rule, "incomplete or incorrect."

Thus, the failure to disclose the truth about Dr. Bourland's work in *Moore* falls squarely within the plain language of Rule 37(c)(1). CPI has not shown that it had "substantial justification" for its failure, nor has it shown that the failure was harmless. The facts show both that there was no justification (as one CPI attorney said, "it just didn't enter my mind") and that the failure caused substantial harm to St. Jude's defense. Sanctions pursuant to Rule 37(c)(1) are warranted here.

Sanctions must be proportionate to the conduct giving rise to them. *Langley v. Union Elec. Co.*, 107 F.3d 510, 515 (7th Cir. 1997) (affirming exclusion of evidence as sanction, which resulted in summary judgment for defendant where plaintiff was at fault for losing key evidence); *Newman v. Metropolitan Pier & Exposition Auth.*, 962 F.2d 589, 591 (7th Cir. 1992) (affirming dismissal where plaintiff failed to appear for deposition in district where suit was pending). CPI tries to characterize the wrong here as "a false answer given by an expert witness to a single question at a deposition." Docket No. 846 at 32. That is literally true, but a truthful answer to that single question would have unlocked a door to important evidence, including valuable impeachment

material to undermine the credibility of the single most important witness in plaintiff's case.

An order striking Dr. Bourland's testimony would have the effect of directing judgment as a matter of law finding no infringement of the '472 patent. That would be a severe sanction. It would certainly be warranted if the court were convinced that CPI's counsel had actual knowledge of Dr. Bourland's deception. There is evidence that would support such a finding. CPI's different lawyers—both inside counsel and outside counsel with McAndrews Held & Malloy—had all the knowledge they needed to recognize Dr. Bourland's deception. They had all the knowledge they needed to prevent the court from treating Dr. Bourland's deception too gently before the jury.

The court ultimately does not disbelieve the lawyers' testimony that they failed to recognize Dr. Bourland's deception. Hall, Malloy, and Sherry failed to put the pieces together. Instead, they spent much more time worrying about "damage control" than about actually clearing up the situation for the court. That degree of fault can still be sufficient fault to trigger sanctions, however. *See Langley*, 107 F.3d at 514 (affirming sanctions amounting to judgment on merits where plaintiff demonstrated poor judgment, "a degree of indolence, as well as a lack of candor" in losing key evidence and failing to report the loss).

Even so, striking Dr. Bourland's testimony is not outside the bounds of reasonable sanctions in this case. In *Newman*, the Seventh Circuit explained: "If the failure is inadvertent, isolated, no worse than careless, and not a cause of serious inconvenience either to the adverse party or to the judge or to any third parties, dismissal (if the failure is by the plaintiff) or default (if by the defendant) would be an excessively severe sanction." 962 F.2d at 591. Dr. Bourland's conduct was deliberate. The failures of CPI and its attorneys were not isolated. They were repeated. In addition, the result of their

failures was not merely "inconvenience" but a serious undermining of the integrity of these proceedings, resulting in a huge expense and effort that may turn out to have been wasted.

As explained earlier in this entry, the court has found for other reasons that CPI is not entitled to prevail on its claims under the '472 and '288 patents. If those other reasons were to be rejected by a reviewing court, however, the sanction of striking Dr. Bourland's testimony and effectively granting judgment as a matter of law for defendants would be too severe in this situation. Rather, the remedy can be tailored more closely to the harm caused, which would be the need for a new trial.

There is no doubt in the court's mind that a new trial is called for on most issues as to which CPI prevailed in the trial tainted by Dr. Bourland's false testimony. The only exceptions are the double patenting defense to the '472 patent, which presents a question of law based only on the two patents, and infringement of Claim 1 of the '472 patent, which depends on claim construction.

A key witness's perjury or deliberately false testimony on a material matter provides sufficient grounds for a new trial if the trial court believes, as this one does, that the result was the denial of a fair trial. *See, e.g., Antevski v. Volkswagenwerk Aktiengesellschaft*, 4 F.3d 537, 540 (7th Cir. 1993) (affirming denial of new trial where perjury not shown: "If a verdict is based on false testimony, the district judge has the discretion under Rule 59 to grant the injured party a new trial."); *Phillips v. Crown Central Petroleum Corp.*, 556 F.2d 702, 705 (4th Cir. 1977) (trial court abused discretion by failing to consider witness's admittedly false testimony when deciding whether to grant new trial); *Stamps v. United States*, 406 F.2d 925, 928-29 (9th Cir. 1969) (trial court erred by failing to grant new trial on charges supported by testimony of witness as to whom there was a "serious

question" of perjury); 12 *Moore's Federal Practice* § 59.13[2][c][iii] (3d ed. 2000) ("false testimony or perjury by a witness may be grounds for a new trial if the falsity of the testimony is established"). *See also Viskase Corp. v. American National Can Co.*, 261 F.3d 1316, 1324 (Fed. Cir. 2001), in which the Federal Circuit affirmed in relevant part a new trial order under Fed. R. Civ. P. 60(b)(3) where a party's expert lied about his presence during testing of defendant's products. Although the plaintiff who called him was not aware of the perjury, his false testimony "irretrievably tainted" the verdict. *Viskase Corp. v. American National Can Co.*, 979 F. Supp. 697, 705 (N.D. Ill. 1997), *aff'd in relevant part*, 261 F.3d at 1324.

Dr. Bourland's deliberately false testimony easily satisfies this standard. CPI itself, in its effort to avoid having Dr. Bourland's testimony stricken, concedes his obvious importance. CPI describes his testimony as "critical evidence." Docket No. 846 at 30 & n. 23.[44]

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[44] In applying Fed. R. Civ. P. 60(b)(3), which authorizes relief from judgment for "fraud . . . misrepresentation, or other misconduct of an adverse party," the Seventh Circuit has made clear that the misconduct must be attributable to a party. Writing broadly, the court described expert witnesses as "free agents." "Parties and counsel have an obligation not to deceive the court about the witness and to correct statements they know to be false, but they are not responsible for the details of the witness's testimony. Rule 60(b)(3) therefore does not apply to the attack on Levy, and the objectors must establish that his testimony 'created a substantial danger of an unjust result.'" *Metlyn Realty Corp. v. Esmark, Inc.*, 763 F.2d 826, 833 (7th Cir. 1985) (district court did not abuse discretion by denying relief under Rule 60(b) based on expert's incorrect, but not willfully false, testimony that did not affect court's ultimate decision). This court is not invoking Rule 60(b)(3), but

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The Supreme Court has explained that a federal court has inherent power "to vacate its own judgment upon proof that a fraud has been perpetrated upon the court." *Chambers v. NASCO, Inc.*, 501 U.S. 32, 44 (1991), *citing Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), and *Universal Oil Products Co. v. Root Refining Co.*, 328 U.S. 575, 580 (1946). This "historic power of equity to set aside fraudulently begotten judgments," *Hazel-Atlas*, 322 U.S. at 245, is necessary to the integrity of the courts, for "tampering with the administration of justice in [this] manner . . . involves far more than an injury to a single litigant. It is a wrong against the institutions set up to protect and safeguard the public." *Id.* at 246. The Supreme Court in *Chambers* limited the use of some exercises of a court's inherent power, such as an award of attorney fees, to instances of bad faith. 501 U.S. at 49-50. However, that limitation does not require a finding that a party (as distinct from a witness—even a hired expert witness) acted in bad faith in order to set aside a verdict and order a new trial based on deliberately false testimony. That power falls well within the established grounds for granting a new trial.

For reasons explained above in this entry—the court's findings that the '472 and '288 patents are invalid, as well as the jury's determination that the '288 patent was not infringed—the court finds that St. Jude is entitled to judgment in its favor on all claims remaining in this case, and that there

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finds that Dr. Bourland's deception and CPI's failure to recognize it and disclose it require a new trial under Rule 59 in order to ensure a fair trial. This situation also satisfies the more stringent test of Rule 60(b)(6) by creating, in the terms of *Metlyn Realty*, "a substantial danger of an unjust result."

is no need for a new trial. However, if any claim by CPI that was tried to the jury survives an appeal, Dr. Bourland's deception entitles St. Jude to a new trial. His actions, and CPI's and its lawyers' failures to correct that deception, seriously undermined the fairness and integrity of the proceedings. St. Jude is entitled to a new trial untainted by Dr. Bourland's deception.

The court also finds that if a new trial is necessary after an appeal, an appropriate sanction under Rule 37(c)(1) would be to require CPI to pay St. Jude for a substantial portion of St. Jude's costs and attorney fees incurred in the first trial and the final stages of preparing for that trial, and in the post-trial motions practice and possible appeals. The court views this sanction as more closely tailored to the harm than would be a decision striking Dr. Bourland's testimony and then granting judgment as a matter of law on that truncated record. Such a substantial sanction is warranted in this case because the proper and prompt disclosure of the "incomplete or incorrect" portion of Dr. Bourland's deposition testimony would have disclosed his report in *Moore v. Medtronic* and avoided the continued deception that results in the conditional order for a new trial.

Because this prospect is contingent on the outcome of any appeal, and because the court cannot determine at this time the scope of any new trial that might actually become necessary, it would be premature at this time to try to specify the amount of such a contingent sanction. The principle that would guide the court, if such a determination must be made in the future, would be to require CPI to compensate St. Jude for efforts wasted as a result of Dr. Bourland's deception.

Based on the court's experience, it would not be surprising for the sanction to reach into seven figures.[45]

St. Jude has already incurred some substantial expenses and fees as a result of the discovery violation, including its efforts to conduct the post-trial discovery and to brief this issue and the related portion of CPI's motion for a new trial. There is nothing contingent about those expenses. St. Jude has submitted a petition for such expenses, and by separate entry today, the court is awarding sanctions totaling $376,917.63.[46]

As explained in the court's Entry on Post Judgment Motions being issued today, however, the court also finds that this is an "exceptional case" under 35 U.S.C. § 285 with re-

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[45] The court is not awarding all expenses associated with the first trial at this time. Notwithstanding St. Jude's arguments to the contrary, the court must assume that the trial would have gone forward even if Dr. Bourland and CPI had disclosed his report in the *Moore* case.

[46] In light of the bad faith requirement in *Chambers*, 501 U.S. at 49-50, the court's conditional award and the award of post-trial fees and expenses relating to Dr. Bourland are not based on the court's inherent power.

As explained in the court's Entry on Post Judgment Motions being issued today, however, the court also finds that this is an "exceptional case" under 35 U.S.C. § 285 with respect to the intentionally false testimony by Bourland and the failures of CPI's inside and outside counsel to remedy that false testimony. *See generally, e.g., Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (finding that case is "exceptional" may be based on conduct that includes misconduct during litigation).

spect to the intentionally false testimony by Bourland and the failures of CPI's inside and outside counsel to remedy that false testimony. *See generally, e.g., Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (finding that case is "exceptional" may be based on conduct that includes misconduct during litigation).

X. CPI's Motion for a New Trial on Infringement of the '288 Patent

The jury found that Claims 4 and 13 of the '288 patent on "multimode" operation of an ICD were not infringed. CPI has moved for a new trial on the issue of infringement. CPI argues it was denied a fair trial in two respects. First, CPI claims that St. Jude's references in opening statement to CPI's desire to "put us out of business" denied CPI a fair trial. Second, CPI claims that the actions taken at trial to remedy Dr. Bourland's deception denied CPI a fair trial.[47]

The court's rulings that the '288 patent is invalid as a matter of law because of the "best mode" violation and obviousness should avoid any possible need for a new trial. However, if those decisions were to be reversed on appeal, it would be necessary to address CPI's motion for a new trial, so the court does so at this time. CPI's motion for a new trial is denied.

A. St. Jude's Opening Statement

In the court's preliminary instructions, the court told the jury that a patent gives the inventor the right to exclude others from making, using, and selling the patented invention

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[47] CPI's motion is addressed in Docket Nos. 840, 841, 842, 864, 873, and 881. The issues concerning Dr. Bourland's testimony are also addressed at length in the submissions on St. Jude's motion on the subject.

throughout the United States for a period of time. During its opening statement, CPI reminded the jury of that right to exclude. Tr. 9, 19.

During its opening statement, St. Jude's counsel said several times that CPI was trying to put St. Jude out of business:

> We're here now to keep ourselves and to keep our people and to keep our products available in the marketplace, because, in fact, the only two people in their players today, as you saw from their chart as who has sales, are Medtronics and CPI. And we're the little guy, and they want to keep us out. They don't want to compete in the marketplace with our products. What they want to do is put us out of business.
>
> St. Jude takes these charges of infringement very, very seriously. We do respect the valid patent rights of others. That's why we were sending checks. Our deal said send the checks, and we believed it was valid. Far different picture than painted for you before.
>
> We did want to continue having that license; but, on the other hand, we are not going to lie down and play dead when somebody shoots a shotgun over the decks and says, We're going to put you out of business, run you out of business and deny patients and doctors your product.
>
> CPI did not want to compete in marketplace. They licensed everything, and we're in the middle. Not because our product was unsafe. You won't hear a word of that. Not because our product is untested. The purpose is pure and simple: to put us out.

Tr. 50-51.

CPI did not object to any of these statements during the opening statement or immediately afterwards. St. Jude's opening statement was the final portion of the first trial day. The next morning, June 12th, CPI moved for a mistrial based on these statements.

The court denied the motion for a mistrial, noting that CPI had failed to make any timely objection to any of the references. Even if CPI's failure to object to the first reference were to be excused, that could not excuse the failure to object to the second, third, and fourth references. The court also noted that CPI itself had correctly told the jury that a patent gives the patentee the right to exclude others from practicing the invention. The court therefore said that putting defendants out of the ICD business was "on the table in this case." Tr. 213-14. The court added that jurors "are usually pretty good at recognizing that their verdicts may have some repercussions, and it seems to me that a curative instruction noting that their job is to focus on damages is sufficient in this case." Tr. 214.

CPI argued that no corrective instruction would be sufficient to cure the harm it claimed from St. Jude's opening statement, but CPI proposed a corrective instruction as an alternative remedy. CPI's proposed instruction read:

> During opening statements, Mr. Swenson stated several times that plaintiffs were trying to put defendants out of business. He also stated that people would lose their jobs and that patients would be denied defendants' products. All of these statements were improper and untrue and should not be considered by the jury. No matter the outcome of this lawsuit, defendants will not be put out of business. No matter the outcome of this lawsuit, people will not lose their jobs. No matter

> the outcome of this lawsuit, patients will not be harmed.

Docket No. 729. In light of both (a) a patentee's right to exclude others from practicing the invention and (b) CPI's contention that both patents were "entry barrier" patents for ICDs, that proposed instruction actually would have misled the jury. The court rejected CPI's proposal and instead instructed the jury:

> Ladies and gentlemen, one thing I just want to point out. Yesterday during—an issue has arisen about some comments made during the defendant's opening statement yesterday. I want to point out to you that if you ultimately rule in favor of the plaintiffs the only form of relief you may consider is an award of damages. As the jury you may not order the defendants to change their conduct.

Tr. 217.

CPI contends now that St. Jude's opening statement and the court's response to it denied CPI a fair trial. At least outside the context of death penalty cases (and often not even in those cases), it is rare for an improper remark in an opening statement to be so egregious as to require a new trial. *See Mayall v. Peabody Coal Co.*, 7 F.3d 570, 573 (7th Cir. 1993) (statements in closing arguments rarely require a new trial); *Moylan v. The Meadow Club, Inc.*, 979 F.2d 1246, 1250-51 (7th Cir. 1992) (same). This is especially true when the remark was not the subject of a timely objection. As Professors Wright and Miller have written, most motions for new trials on such grounds are denied "because the conduct complained of, under the circumstances, was not misconduct, because it was not prejudicial, because it was not objected to, or because any prejudice was cured by the instructions of the court." 11 Wright & Miller, *Federal Practice & Procedure*

§ 2809 (2d ed. 1995). All four of these reasons apply with substantial force in this case.

First and second, St. Jude's comments did not amount to serious misconduct and were not unfairly prejudicial to CPI. In the court's view, the only thing that was factually inaccurate about the disputed portion of St. Jude's opening statement is the assertion that plaintiffs sought to put St. Jude out of all of its business rather than only the ICD business. Plaintiffs were claiming that the patents in question are "entry barrier" patents and that all of St. Jude's ICDs infringe both patents. The jury was told with both sides' consent that a patent gives the patentee the right to exclude others from manufacturing or selling infringing devices. CPI said in its opening statement that it wanted St. Jude to stop infringing. Tr. 25. In addition, CPI's entire theory for lost profit damages was based on the assumption that St. Jude should not have been and would not have been in the ICD market at all. The court found that St. Jude's references to "out of business" were improper exaggerations because they were not limited to the ICD business. Tr. 213. Nevertheless, the jury might well have understood the references in context as limited to the ICD business.

CPI relies on two Seventh Circuit decisions that ordered new trials based on references to the effects of a verdict, but both cases involved different and substantially worse problems. In *Adams Laboratories, Inc. v. Jacobs Engineering Co.*, 761 F.2d 1218, 1224-26 (7th Cir. 1985), the plaintiff's lawyer violated a pretrial order *in limine* prohibiting references to plaintiff's bankruptcy and other matters involving the parties' relative financial strength and the consequences of a verdict. Also, the defendant in *Adams Laboratories* promptly objected to the misconduct. In *Joseph v. Brierton*, 739 F.2d 1244, 1246-48 (7th Cir. 1984), the defense managed to make unfair use of a pretrial ruling. The defense obtained from the trial court an order that barred the plaintiff

from telling the jury that the individual defendants would be indemnified by the state. The defense attorney in closing then argued how unfair it would be to saddle the individual defendants with the financial consequences of a prisoner's death. Although the plaintiff did not object until after closing to this unfair misuse of the order *in limine*, the district judge agreed that an objection during the argument would have violated the court's pretrial ruling, so the usual obligation to object did not apply. *See* 739 F.2d at 1247. Neither case is comparable to this case, where St. Jude's comments did not violate any pretrial ruling, and in fact addressed an issue that CPI's own opening statement put on the table—its right to exclude St. Jude from the ICD market.

CPI argues that the jury's inquiry during deliberations shows prejudice here. The jury asked one question: When does the '472 patent expire? From that question, CPI infers that the jury wanted to make sure that no injunctive relief shutting down St. Jude's ICD business would be available. That theory reads far too much into the question. The court instructed the jury to consider all the claims separately. Because the jury found infringement of the '472 patent but not the '288 patent (on which the infringement claim was extremely weak), the scope of the infringing sales was limited. Neither side, perhaps understandably, gave the jury explicit guidance on what to do in the event it reached such a split result. To be consistent with its verdict and the court's instructions, the jury needed to reduce the time frame for the damages it was awarding. The court does not recall that the jury heard anything about injunctive relief. CPI's argument is highly speculative, especially where a perfectly innocuous explanation for the jury's inquiry, based on conscientious attempts to follow instructions in calculating royalties, provides the more likely explanation.

In short, under all the circumstances here, the court does not find that the comments in St. Jude's opening statement were so serious or prejudicial as to require a new trial.

Third, the lack of a timely objection also weighs heavily against a new trial. CPI tries to excuse its failure to object during the opening statement, when any curative instruction would have had the greatest effect. Perhaps the best response to this argument comes from CPI itself, when it addressed St. Jude's challenge to attorney Malloy's treatment of Dr. Bourland's problem during closing argument:

> Even were Mr. Malloy's closing argument otherwise subject to challenge, St. Jude's failure to object in a timely manner to the alleged mischaracterization of Dr. Bourland's testimony constitutes a waiver of any subsequent objection. *See, e.g., Valbert v. Pass*, [866 F.2d 237, 242 n.7 (7th Cir. 1989)] (challenge to closing argument rejected because no objection to the allegedly improper comments was made at trial.) citing *Deppe v. Tripp*, 863 F.2d 1356, 1364 (7th Cir. 1988). At no time during plaintiffs' closing argument did St. Jude's counsel object to the argument as improper.

Docket No. 846 at 19. Hanging from CPI's citation to Deppe was a footnote:

> *Accord Miksis v. Howard*, 106 F.3d 754, 764 (7th Cir. 1997); *Doe v. Johnson*, 52 F.3d 1448, 1465 [(7th Cir. 1995)]; *Carmel v. Clapp & Eisenberg, P.C.*, 960 F.2d 698, 704 (7th Cir. 1992); *United States v. Fearns*, 501 F.2d 486, 489 (7th Cir. 1974); *Datskow v. Teledyne Continental Motors Aircraft Products*, 826 F. Supp. 677, 687 (W.D.N.Y. 1993) (noting Fifth Circuit's holding in *Nissho-Iwai Co. v. Occi-*

> *dental Crude Sales, Inc.*, 848 F.2d 613, 619-20 (5th Cir. 1988) that it is reversible error to grant a plaintiff's motion for a new trial based on admittedly improper statements during defendant's summation when the plaintiff failed to object either during the argument or at a sidebar conference immediately thereafter).

Docket No. 846 at 19 n.5.

CPI has not cited any civil case comparable to this one, in which a party was held entitled to a new trial after failing to object during or after an opening statement (or closing argument, for that matter), but waiting until the next day. *See, e.g., Gonzalez v. Volvo of America Corp.*, 752 F.2d 295, 298 (7th Cir. 1985) (per curiam) (new trial not required when defendant failed to object to "grossly immoderate" closing argument that violated pretrial order, referred to defendant's corporate status and wealth, and asked jurors to place themselves in plaintiff's shoes), citing *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 238-39 (1940).

Fourth, to the extent that St. Jude's opening posed any risk of unfairness to CPI, the court believes its instructions were sufficient to cure the problem. CPI complains about the court's curative instruction given after the court denied the motion for a mistrial. CPI did not make these specific points when the court could have considered them. *See* Tr. 215-16. But the very defects CPI claims—the absence of a more specific reminder of exactly what St. Jude said and a specific instruction to disregard it—would have exaggerated the risks that CPI itself complains about--that the instruction would have emphasized the weight of the remarks CPI found objectionable. Moreover, CPI's own proposed curative instruction would have been a deceptive exaggeration. It would have been far more objectionable than the comments from St. Jude that it was offered to "cure."

In light of the delay resulting from CPI's failure to raise a prompt objection, the more useful curative instruction the court gave was the standard instruction, both at the beginning of trial and in final instructions that statements of counsel in argument are not evidence. As CPI itself has argued: "The courts of this Circuit have 'repeatedly found that jury instructions of this sort mitigate any prejudicial effect of potentially improper remarks made by counsel during closing argument.'" Docket No. 846 at 20, quoting *Jones v. Lincoln Electric Co.*, 188 F.3d 709, 732 (7th Cir. 1999), and citing *Valbert v. Pass*, 866 F.2d 237, 241 (7th Cir.1989). The same applies to opening statements, and the court agrees with CPI on this point.

Trials are not perfect, and re-trials create opportunities for new problems. Thus, only the rarest of civil cases would require a new trial based on remarks during opening or closing. *See United States v. Schimmel*, 943 F.2d 802, 805-06 (7th Cir. 1991) (no new trial in criminal case where remarks were made during opening statement of three day trial; trial court instructed the jury that statements made by lawyers during opening and closing arguments were not to be considered as evidence and should not be considered by them in arriving at their verdict, and appellate court assumed that the jury followed the court's cautionary instructions); *Canada Dry Corp. v. Nehi Beverage Co.*, 723 F.2d 512, 526-27 (7th Cir. 1983) (affirming denial of new trial based on improper vouching in closing argument). St. Jude's opening statement does not require a new trial in this case.[48]

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[48] If any attorney statement in this case was sufficient to trigger a mistrial, it came from CPI attorney Malloy. He waited to make the statement until the last two minutes of the rebuttal portion of his closing argument, when St. Jude no longer had any opportunity to respond. Malloy chose that moment to refer to "hidden docu-

[Footnote continued on next page]

With respect to the "little guy" issue that CPI now finds objectionable in St. Jude's opening, CPI itself put the market share data into evidence, showing that Medtronic and CPI were the two biggest players in the market, and that Ventritex St. Jude had no more than about 10 percent of the market. The jury obviously knew it was dealing with large corporations on both sides of the case. St. Jude's reference to this fact could not have been prejudicial, let alone so prejudicial as to require a mistrial, especially in the absence of a contemporaneous objection.

CPI also complains about testimony that CPI itself elicited from the president of St. Jude's cardiac rhythm management division, Michael Coyle. CPI's lawyer asked Coyle whether an award of the damages CPI was seeking would put St. Jude medical out of business. *St. Jude objected to the question.* The court overruled the objection, and the witness answered: "The damages that were requested were very, very significant, especially relative to the values and the transactions that we did here. It is entirely possible that the negative impact of the transaction on our ability to generate earnings per share could result in our inability to remain a stand-alone company." CPI's lawyer then asked: "Not going to cause you to go bankrupt, is it?" St. Jude again objected. The court overruled the objection, and Coyle said "I don't think so." Tr. 2203-05. St. Jude reminded the jury of this exchange during closing arguments. Tr. 3411.

[Footnote continued from previous page]

ments" to support a new theory of "copying." Tr. 3483. St. Jude's attorney objected immediately, and the court instructed the jury to disregard the poisonous and unjustified reference to "hidden documents."

The court has never before seen a party who elicited testimony over an objection from the other side then move for a mistrial based on that testimony. *See Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1469-71 (Fed. Cir. 1997) (affirming denial of new trial based on testimony that moving party itself elicited and to which it made no timely objection). St. Jude's objections to the questions to Coyle are a good sign that his answers were not evidentiary "harpoons" that he was primed to launch at the slightest invitation. This evidence elicited by CPI does not support a new trial for CPI.

B. CPI's Objections to Treatment of Dr. Bourland's Report

As its second basis for a new trial on the '288 infringement issue, CPI claims that the court allowed defendants to distort Dr. Bourland's report in the *Moore* case. CPI attacks the presentation St. Jude made after the court informed the jury that the failure to disclose the report had been improper. *See* Tr. 2891-95.

There is no doubt that the remedy during trial for Dr. Bourland's deception (which the court did not then know was intentional) was improvised. The improvisation resulted from the timing of the unexpected disclosure of Dr. Bourland's report in the *Moore* case and from Dr. Bourland's travel plans—or what the court and St. Jude knew about his travel plans, rather than what CPI's attorneys knew but failed to disclose about those travel plans.

Of course, if Dr. Bourland had told the truth in his deposition or at trial, or if he had remained available to be recalled, or if CPI had informed the court and St. Jude that Dr. Bourland was returning to Indiana before the conclusion of the trial, perhaps none of this would even have been necessary. Honest answers and timely responses would have allowed confrontation at trial, in front of the jury, the way the justice system is supposed to work. Dr. Bourland's decision

to lie in order to conceal the substance of his work in *Moore* prevented that process from working.

Moreover, CPI and its lawyers had all the information they needed to correct the problem much earlier. The inside lawyers had a copy of Dr. Bourland's report in *Moore*. The outside lawyers knew of the *Moore* case, knew it had not been resolved by the time of this trial, and should have known that if Dr. Bourland was being deposed in the *Moore* case, he almost certainly had prepared an expert report. This failure cannot be laid at the feet of St. Jude or the court.

In any event, the court found at trial that St. Jude's demonstrative exhibits were "substantially and fairly accurate in summarizing or quoting Dr. Bourland's reports and relevant testimony." Tr. 2882-83. Also, the jury had before it Dr. Bourland's actual testimony in this case and, ultimately without objection from CPI, his full report in the *Moore* case. With the actual evidence before it, CPI's post-trial arguments about counsel's summary presentation are comparable to a difficult argument that an opponent's closing argument so distorted the actual evidence as to require a new trial—despite the absence of an objection and despite the court's instruction that counsel's arguments were not evidence.

CPI highlights the difference between "frequent" and "occasional" in demonstrative exhibit 8601A. However, that difference was immaterial to the relevant point, which was Dr. Bourland's contradictory approaches to whether the reliability of a detecting or determining means in avoiding unnecessary shocks was relevant *at all* to an equivalence analysis. At trial in this case, Dr. Bourland insisted (untenably) that the reliability of a determining means had nothing to do with the "result" prong of the equivalence analysis. *See* Tr. 963-65. For purposes of this case, there was also no need to address the details of Dr. Bourland's discussion of the "onset" issue in the *Moore* case, which Dr. Bourland did not deem relevant to his broad-brush opinion in this case that

rate-only and rate-plus-PDF circuitry were equivalent determining means.[49]

CPI's discussion of the treatment of the Rockland '140 patent tries to obscure the relevant point. For purposes of obviousness of the '288 patent, the relevant point is that Rockland '140 described a type of therapy that it called "cardioversion" using simultaneous but relatively low energy shocks. In *Moore*, Dr. Bourland concluded that the combination of such an implantable "cardioverter" and a pacemaker from Rockland '140 and the combination in external devices with cardioversion and defibrillation capacity rendered obvious an implantable cardioverter defibrillator with a pacemaker. Ex. 4051 at 33. Whether the term "cardioversion" had exactly the same meaning in Rockland '140 and the '288 patent, which is what CPI now contests, is beside the point.

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[49] The evidence showed that St. Jude's products produce unnecessary shocks for approximately 16 percent of patients per year. Tr. 2334 (Dorian). CPI claims now, and argued to the jury in closing, that the evidence showed that the devices using the rate-plus-PDF detection means of the '288 patent produce unnecessary shocks at a lower rate of 10 percent. *See* Tr. 3363-64. CPI has distorted Dr. Bourland's testimony on this point. His figure of 10 percent was for the difference in the rate of unnecessary shocks as between the two types of determining means. Tr. 963-65. Although the testimony was very loose from a statistical standpoint, Dr. Bourland was not claiming an absolute rate of 10 percent for unnecessary shocks. He agreed that rate-only devices produced fewer unnecessary shocks than rate-plus-PDF devices. *Id.* He also agreed "that the use of rate alone, as St. Jude uses rate, gives many fewer shocks than the use of PDF alone, or the use of PDF with rate." Tr. 959.

Of course, with respect to all the objections CPI is raising now, it had the opportunity to raise objections at the time and to argue the evidence to the jury. (CPI did object to the "frequent/occasional" problem at the proper time.) Perhaps not surprisingly, though, CPI chose not to focus the jury's attention on Dr. Bourland's problems. CPI chose instead to rely on the now debunked explanation that he had "forgotten" about his work in the *Moore* case.

Finally, the fact remains that the evidence was overwhelming that the '288 patent's rate-plus-PDF determining means are not equivalent to St. Jude's rate-only binning algorithm. CPI's infringement case on the '288 patent was extremely weak. CPI had a fair opportunity to present its strained theories, and the jury rejected them. There would be no point in a new trial on the issue.

XI. Royalties and Damages

The parties' post-verdict motions also challenge the jury's resolution of several damages issues. After finding that the '472 patent had been infringed but the '288 patent had not, the jury rejected CPI's claim for lost profits. The jury then found that a reasonable royalty for the '472 infringement would have been an initial payment of $110 million plus a running royalty of $30 million from May 15, 1997 through the expiration of the '472 patent in March 2001.

St. Jude has moved for judgment as a matter of law holding that CPI is not entitled to the $110 million initial royalty payment. In the alternative, St. Jude seeks a new trial on that issue. St. Jude also seeks a new trial on the amount of running royalty. CPI has filed a contingent motion for a new trial asking that if the court sets aside any portion of the dam-

age award, a new trial include the issue of lost profits as well as royalties.[50]

Under the court's findings that the '472 patent is invalid and not infringed, of course, no damages of any kind should be awarded. In the event that a reviewing court were to disagree as to invalidity and infringement, however, the damages award would present an issue that required decision. In that event, the court conditionally grants St. Jude's motion for a new trial on the issue of royalties and denies CPI's contingent motion to have such a new trial also include the issue of lost profits.

A. The $110 Million Initial Payment

When a defendant is found liable for infringing a patent, "the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty." 35 U.S.C. § 284. One established method for determining a reasonable royalty is to consider the results of a hypothetical negotiation between the parties when the infringement began. *See Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1121 (S.D.N.Y. 1970), *modified*, 446 F.2d 295 (2d Cir. 1971); *accord*, *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1384-85 (Fed. Cir. 2001); *Unisplay, S.A. v. American Electronic Sign Co.*, 69 F.3d 512, 516 (Fed. Cir. 1995). The parties here presented expert opinions on the results of such a negotiation.

Determining a reasonable royalty under the artificial conditions of the hypothetical negotiation is not an exact sci-

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[50] St. Jude's motion is briefed in Docket Nos. 817, 853, and 866. CPI's contingent motion is briefed in Docket Nos. 852, 870, and 880.

ence. *See Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341, 1353 n.5 (Fed. Cir. 1999) (approving district court's "honest" description of its royalty finding as its "best estimate"). The task necessarily involves an element of approximation and uncertainty. *Unisplay*, 69 F.3d at 519 (jury not limited to using a figure proposed by one of the parties during trial). Doubts about the amount should be resolved against the infringer. *State Industries, Inc. v. Mor-Flo Industries, Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983).

CPI relied on the testimony of Thomas Evans, an experienced licensing executive and expert witness, to offer an opinion on a reasonable royalty in this case. Evans testified that a reasonable royalty for a one-way non-exclusive license to both the '472 and '288 patents would have included an initial payment of $100 million, plus a running royalty of 13 percent of sales revenue. Evans based his opinion on the assumption that both patents were so-called "entry barrier" patents, meaning that any ICD would have needed to incorporate the features of external programmability and multimode programming, and would have had to infringe the '472 and '288 patents in order to compete successfully in the market.

To the extent that St. Jude is arguing that, as a matter of law, no initial payment could have been reasonable, the court disagrees. The evidence shows at least some support for an initial payment, although at much more modest levels. There is no principled reason why such a payment of some amount might not have been a reasonable outcome of the hypothetical negotiations. Some other deals in the industry had involved initial payments, though they either were credited toward running royalties or resolved prior disputes. The court therefore declines to hold that a reasonable royalty could not have included any initial payment.

St. Jude is entitled to a new trial on the issue of a royalty, however. The overwhelming weight of the evidence shows that the jury's royalty award was grossly excessive. Evans' opinion that an initial payment of $100 million would have been reasonable was based on at least two critical assumptions that are contrary to the manifest weight of the evidence.

First, and most simply, Evans assumed that the negotiations would have been for two patents, not one that was due to expire in just four years. The jury found that the '288 patent was not infringed, and the '472 patent was due to expire in March of 2001, about four years after the Ventritex merger closed. Evans offered no guidance as to how the initial payment could have been even larger than his $100 million proposal if only one patent had been involved.

The second major assumption that has been undermined concerns the precise timing of the hypothetical negotiations. Evans assumed that the hypothetical licensing negotiations would have occurred when St. Jude was already over a barrel, after it had closed on its merger with Ventritex deal. *See* Tr. 1517 (St. Jude's bargaining position would have been "very weak" because it had "invested more than 300 million dollars in their acquisition of Ventritex."); Tr. 1600 (St. Jude would have had to take the deal proposed by Evans "because of the investments they had made and the expectations they had.").

Ventritex had been competing in the ICD market with a valid license to the entire portfolio of Mirowski patents, including the '472 patent. By the terms of CPI's license agreement with Ventritex, that license terminated upon a change in control of Ventritex. St. Jude had sought to avoid the potential patent problem by acquiring a separate license to the Mirowski patents by acquiring the license and other assets from Telectronics in late 1996. That effort to acquire a license from Telectronics was also the subject of litigation and has thus far been unsuccessful in arbitration and the courts. *See*

Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 149 F. Supp. 2d 610 (S.D. Ind. 2001) (granting CPI's motion for summary judgment rejecting St. Jude's license defense). In essence, through two separate acquisitions, St. Jude tried to acquire a license from Telectronics, which could then be used by Ventritex after the St. Jude merger.

The St. Jude-Ventritex merger was eventually scheduled to close on May 15, 1997. All Ventritex sales of ICDs were made under a valid license prior to that date. Evans assumed, at least initially, that the hypothetical royalty negotiations would have occurred immediately after St. Jude had closed on the Ventritex merger on May 15, 1997. St. Jude and its expert, Dr. Allyn Strickland, argued that the hypothetical negotiations would have occurred before the Ventritex closing. Under that scenario, if CPI had demanded unreasonable royalties, St. Jude would have had the option of walking away from the negotiations, in which case Ventritex would simply have continued to compete with CPI and Medtronic.

A key factor in determining the reasonable royalty in the hypothetical negotiation is the economic effects of non-infringing choices available to the infringer, such as stopping production, redesigning its product to avoid infringement, or substituting some other non-infringing alternative. *See, e.g., Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1571-72 (Fed. Cir. 1996) (reversing high royalty rate and remanding for reconsideration in light of available non-infringing alternative); *State Industries, Inc. v. Mor-Flo Industries, Inc.*, 883 F.2d 1573, 1581 (Fed. Cir. 1989) (affirming royalty rate based on finding that potential licensee would have used less attractive non-infringing alternative allowing for some profit rather than paying higher rate that would create higher risk of losing money). The costs of such options are important factors to

consider in establishing some reasonable upper limits on a reasonable royalty.[51]

This case differs from the run of the mill because Ventritex already had a valid license and could have continued to compete under that license as long as control of the company did not change. If St. Jude had the knowledge assumed for purposes of the hypothetical negotiations--that the '472 patent was valid and would be infringed, meaning that the Telectronics license would not have transferred—then St. Jude would have had the option of simply not going forward with the Ventritex merger. That course would have left Ventritex as a competitor with a valid license for all the Mirowski patents, including the '472 patent.

CPI argues in rebuttal that Evans testified that the results of the hypothetical negotiation would have been the same if it had occurred even months before the Ventritex deal closed.

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[51] That reasoning is the basis for Judge Easterbrook's royalty award in the *Grain Processing* case. Judge Easterbrook's opinion on the royalty rate appears at 893 F. Supp. 1386, 1389-93 (N.D. Ind. 1995) (cost of non-infringing alternative imposed cap on reasonable royalty). That determination was not appealed, though the denial of lost profits was initially vacated and ultimately affirmed in *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341 (Fed. Cir. 1999). The same reasoning based on the cost of non-infringing alternatives, including not competing at all, is also implicit in the *Georgia-Pacific* factors, which assume that the infringer would agree to pay a royalty only if the rate would allow some prospect for a reasonable profit, though no guarantee of an actual profit. *See Georgia-Pacific*, 318 F. Supp. at 1120; *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1555 (Fed. Cir. 1995) (*en banc*) (infringer's actual net profits do not impose upper limit on royalty).

He did in fact so testify. Tr. 1517-18. But his explanation was a non-explanation: "If a negotiation would have occurred in late '96, the negotiation would have been to enable St. Jude Medical to acquire Ventritex and--or to complete the transfer of control of Ventritex and sell the Ventritex products under the umbrella of St. Jude Medical. And to me that enabling negotiation would have been much the same as the negotiation on May 15th, '97." Tr. 1518.

The idea that whether St. Jude had or had not irrevocably committed $300 million to merge with Ventritex would have had no effect on the outcome of the negotiations is untenable. Evans is a very experienced expert witness. He testified on page 1517 that St. Jude's bargaining position on May 15, 1997, would have been "very weak" because it had just invested more than $300 million to acquire a business that would have been worth far less without a valid license. Yet he then testified two minutes later on page 1518 that the result would have been the same before St. Jude had committed the $300 million. That unexplained contradiction shows that the jury's reliance on Evans' opinion on the amount of the initial payment was contrary to the manifest weight of the evidence. The court need not give weight to such "expert" opinions that do not vary with undeniably relevant facts. *See, e.g., Mid-State Fertilizer Co. v. Exchange National Bank of Chicago*, 877 F.2d 1333, 1339-40 (7th Cir. 1989) (affirming rejection of expert opinion that offered no explanation for conclusion).[52]

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[52] CPI tried to argue that St. Jude's expert on royalties, Dr. Strickland, took a similar approach by claiming that his opinion did not depend on whether the negotiations took place before or after the St. Jude Ventritex merger closed. Docket No. 853 at 19 n.11, quoting Tr. 2666-67. He did not. Dr. Strickland testified that his opinion on the results of a royalty negotiation did not depend

[Footnote continued on next page]

To justify the $100 million initial payment, CPI and Evans also relied on the fact that St. Jude obtained from Pacific Dunlop an agreement to indemnify St. Jude for up to $135 million if the Telectronics license to the Mirowski patent portfolio did not transfer with the Telectronics assets. Tr. 1557-58. The amount of that indemnification was a significant piece of evidence in plaintiffs' favor, but it does not justify the huge initial payment awarded by the jury. The Telectronics license would have been a license to the entire Mirowski portfolio. The results of the hypothetical royalty negotiation would have been a license only to the '472 patent, leaving St. Jude open to additional litigation and charges of infringement on other Mirowski patents. The indemnification from Telectronics, while arguably relevant, cannot come close to justifying the initial payment awarded by the jury.

Notwithstanding the weakness of Evans' assumptions, the jury awarded an even larger initial payment than he had proposed. In light of that verdict, the destruction of either of the two assumptions would have been sufficient to require a new trial on the amount of the royalty. When both of the expert's key assumptions were undermined, the jury verdict awarding even more than the expert had proposed was contrary to the manifest weight of the evidence. A new trial on the issue of royalties is necessary.

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on the particular date up to the moment that the merger actually closed. But Dr. Strickland did not express an opinion on the outcome of negotiations occurring after the merger had closed. *See* Tr. 2786-89.

B. The Running Royalty

St. Jude also argues that the jury's award of $30 million in running royalties should be set aside as excessive. That sum amounts to a royalty rate of about 6.3 percent of St. Jude's ICD sales before the '472 patent expired.

The court instructed the jury on the issue of royalties in terms of the outcome of a hypothetical negotiation. The jury followed instructions by breaking down its royalty verdict into two separate numbers-one for an initial payment and another for a running royalty. The court must assume, however, that the jury viewed its two answers as the combined outcome of that single hypothetical negotiation. As explained above, Evans' assumptions affecting the outcome of the running royalty have been thoroughly undermined. Accordingly, St. Jude's motion for a new trial on the amount of a reasonable running royalty is also granted. If a future jury needs to consider the issue of a reasonable royalty, it should consider both aspects together.

The grant of the new trial on royalties is also subject to remittitur. *See, e.g., Unisplay, S.A. v. American Electronic Sign Co.*, 69 F.3d 512, 519 (Fed. Cir. 1995) (applying the "maximum recovery rule," which requires that the remittitur amount be based on the highest amount of damages the jury could properly have awarded based on the relevant evidence). In this case, the number should have been no greater than the 6 percent rate that Ventritex had been paying for its license to the entire Mirowski portfolio. CPI notes that the amount would have been $28 million. *See* Docket No. 853 at 32. Accordingly, in the event that a reviewing court finds that the '472 patent is valid and infringed, and that a new trial is not warranted on other grounds, the court will give CPI an opportunity to accept a reduced amount of total damages of $28 million. If CPI does not accept that amount, then the court will order a new trial on the amount of a reasonable

royalty, including both any initial payment and a running royalty.

C. CPI's Contingent Motion for a New Trial on Damages

A patent owner whose patent has been infringed may recover as damages its lost profits resulting from the infringement. To recover lost profits, the patent owner must show causation in fact, establishing that but for the infringement, it would have made additional profits. *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999), citing *King Instruments Corp. v. Perego*, 65 F.3d 941, 952 (Fed. Cir. 1995). This proof requires the patent owner to reconstruct what most likely would have happened in the market if the infringement had not occurred. *Grain Processing*, 185 F.3d at 1350. A fair and accurate reconstruction of the "but for" market also must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken if it had not infringed. *Id.* at 1350-51.

CPI has moved for a new trial on the issue of lost profits in the event that the court grants a new trial on the issue of royalties, as the court is doing on a conditional basis (in the event a reviewing court sets aside this court's finding that the '472 patent is invalid). CPI bases its contingent request for a new trial on its objection to the court's Final Instruction No. 60 on lost profits, which stated in part:

> To reconstruct fairly and accurately how the market for ICDs would have developed without any infringement, you must also take into account alternative actions the defendants would have undertaken if they had not infringed. An infringing competitor in the marketplace without infringement is not likely to surrender its complete market share when faced with a patent if it can compete in some

> other lawful manner. A product sold under a valid license does not infringe a patent. As you know, Ventritex was licensed to practice the '472 and '288 patents before it merged with St. Jude and Pacesetter. Because the merger caused the termination of that license, any infringement began with the merger. If that merger had not occurred (that is, if the infringement had not occurred), the license would have allowed Ventritex to continue manufacturing and selling its products as an independent company. When reconstructing the market in the absence of the infringement, you may take this possibility into account.

CPI contends that Final Instruction No. 60 misstated the law. As CPI views the case, the option of simply not closing on the St. Jude-Ventritex merger was not a viable non-infringing option for defendants. CPI contends the instruction suggesting that it was such an option misinterpreted the Federal Circuit's decision in *Grain Processing*.

The court believes that Final Instruction No. 60 accurately interpreted the reasoning of *Grain Processing* as applied to the unusual situation in this case. In the more typical infringement case, of which *Grain Processing* was an example, a defendant introduces a new product into the market. The product is later determined to infringe the plaintiff's patent. Nevertheless, the infringement might not have been essential to the defendant's sales, and there might have been other non-infringing alternatives available. *See Grain Processing*, 185 F.3d at 1349 (district court correctly considered in lost profits analysis a substitute that had not actually been sold on the market during infringement period, but which was available and could have been sold instead of the infringing product).

In *Grain Processing*, the issue was which non-infringing products were available during the time of the defendant's infringement. The Federal Circuit's reasoning was broader, however, for it instructed district courts deciding claims for lost profits to require "reliable economic proof of the market that establishes an accurate context to project the likely results 'but for' the infringement." *Id.* at 1356. That reconstruction of the market "must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed." *Id.* at 1350-51.

In *Grain Processing* itself, the alternative was a non-infringing product that was not actually sold during the infringement period. In this unusual case, by contrast, the products in question were already on the market as Ventritex products, which had been manufactured and sold under a valid license from plaintiffs. The event that converted those products and sales into infringing products and sales was the St. Jude Ventritex merger, which had the effect of terminating the Ventritex license. Thus, the available non-infringing alternative in this case was not a redesigned product but a decision not to close on the merger, leaving Ventritex with a valid license to continue as an independent competitor in the market.

CPI argues that this approach will nullify lost profits as a measure of damage because any infringer will simply claim that, with perfect hindsight, it would not have infringed. Docket No. 880 at 1. The argument oversimplifies and misunderstands the court's reasoning. If, in the absence of infringement, the plaintiff would have sold more of its products (because the infringer would have offered a less functional or more expensive or lower quality alternative, for example), lost profits would still be an appropriate measure of at least some damages. The reasoning of *Grain Processing* is not limited, as CPI argues, to substitute technologies. Its reasoning is broader and extends to the unusual circumstances of

this case, in which the reasonable non-infringing alternative was not to close on the merger and to leave Ventritex selling its products under a valid license. Accordingly, the jury reasonably found that no lost profits had been proven. CPI's contingent motion for a new trial on the issue of lost profits is therefore denied.

XII. Conclusion

For the reasons set forth above, defendants are entitled to judgment as a matter of law and a declaration that Claims 1 and 18 of the '472 patent and Claims 4 and 13 of the '288 patent are invalid, and that Claims 1 and 18 of the '472 patent were not infringed. On a conditional basis under Fed. R. Civ. P. 59, and in the alternative, defendants are entitled to a new trial on all issues as to which defendants did not prevail at trial, other than the double patenting defense to the '472 patent and infringement of Claim 1 of the '472 patent. The court also awards sanctions in favor of defendants and against plaintiff Cardiac Pacemakers, Inc. in the amount of $376,917.63, with an additional amount to be determined in the event that a new trial is needed. An amended final judgment shall be entered accordingly.

So ordered.

APPENDIX C

United States Court of Appeals
for the Federal Circuit

CARDIAC PACEMAKER v. ST JUDE MEDICAL,
02-1532, -1559

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the CROSS-APPELLANT, and a response thereto having been invited by the court and filed by the APPELLANTS, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and that the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on November 9, 2004.

FOR THE COURT,

/s/

Jan Horbaly
Clerk

Dated: November 2, 2004